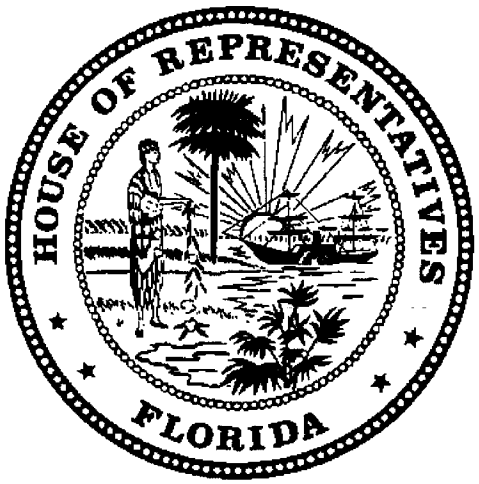

Health Care Regulation Committee

Wednesday, February 22, 2006
10:30 AM - 12:00 PM
212 Knott Building

Allan G. Bense
Speaker

Rene Garcia
Chair

House of Representatives

Committee on Health Care Regulation

AGENDA

February 22, 2006
10:30 AM - 12:00 PM
212 Knott Building

I. Opening Remarks by Chair Garcia

II. Consideration of the following proposed committee bills:

PCB HCR 06-01 – Coordinated Health Care Information

PCB HCR 06-03 – Methamphetamine Contamination

III. Consideration of the following bills:

HB 411 – Psychotherapist-Patient Privilege by Rep. Roberson

HB 439 – Certificate of Birth Resulting in Stillbirth by Rep. Planas

HB 523 – Florida Center for Nursing by Rep. Robaina

HB 587 – Health Care Practitioners by Rep. Galvano

HB 685 – Veterinary Drug Distribution by Rep. Coley

IV. Closing Remarks

V. Adjournment

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HCR 06-01 Coordinated Health Care Information
SPONSOR(S): Health Care Regulation Committee
TIED BILLS: **IDEN./SIM. BILLS:** 1332

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.: Health Care Regulation Committee		Bell	Mitchell
1)			
2)			
3)			
4)			
5)			

SUMMARY ANALYSIS

The Proposed Committee Bill (PCB) on Health Care Information creates the "Coordinated Health Care Information and Transparency Act of 2006." The act changes a number of provisions in current statute to better coordinate health information for purposes of public health, policy analysis, and provide transparency for health care consumers.

The bill renames the Center for Health Statistics in the Agency for Health Care Administration (AHCA) to the Florida Center for Health Information and Policy Analysis. The bill specifies that the Center's role is to identify the best available data sources and coordinate the compilation of health-related data and statistics.

The bill renames the State Comprehensive Health Information System Advisory Council to the State Consumer Health Information and Policy Advisory Council. The bill specifies the Council's duties and responsibilities, which include the following:

- Develop a mission statement, goals, and plan of action for the identification, collection, standardization, sharing, and coordination of health-related data across federal, state, and local government and private sector entities;
- Develop a review process to ensure cooperative planning among agencies that collect or maintain health-related data; and
- Create ad hoc issue-oriented technical workgroups, on an as needed basis, to make recommendations to the Council.

The bill also authorizes AHCA to manage and monitor grants to advance the Florida Health Information Network, requires AHCA to oversee and manage health care data from other state agencies, and requires AHCA to collect data on retail prices charged by pharmacies for 100, rather than 50 of the most frequently prescribed medications. AHCA is required to post the prices for these prescriptions online no later than October 1, 2006.

According to AHCA, there is no fiscal impact to implement the provisions in this bill.

The effective date of the bill is upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Empower Families – Expands the duties of the State Center for Health Statistics to provide more transparency in prescription drug prices by expanding the list of available online prescription drug price from 50 to 100 drugs and provides consumers additional access to information on health care providers.

B. EFFECT OF PROPOSED CHANGES:

Public Reporting

The Proposed Committee Bill (PCB) on Health Care Information changes the terminology used to describe the type of measures the Agency for Health Care Administration (AHCA) publicly reports from performance outcomes to healthcare quality measures and defines those measures to include but not be limited to:

- process measures,
- patient safety measures,
- inpatient quality indicators,
- preventable adverse drug events, and
- performance measures.

The current requirements for public reporting in ss. 408.05 (3)(l) & 408.062(1)(j), F.S., use the terms "performance outcome data" or "performance outcome indicators." There are specific references to the publication of mortality rates, complication rates and infection rates in s. 408.05 (3) (l), F.S.

According to AHCA, the change in terminology and specification of various types of performance measures reflect the variety of types of measures available for public reporting and the development of new measures.

The bill includes the Centers for Disease Control and Prevention as a resource for potential standards to measure health care providers' performance. This change adds a resource for data standards regarding hospital infections and other standards related to the performance of health care providers.

State Comprehensive Health Information System Advisory Council

The PCB changes the name of the State Comprehensive Health Information System Advisory Council to the State Consumer Health Information and Policy Advisory Council and specifies certain responsibilities of the Council in its advisory role regarding the development of the comprehensive health information system.

The bill specifies that the Council will advise the Agency for Health Care Administration (AHCA) regarding the identification, collection, standardization, sharing, and coordination of health-related data, including fraud and abuse data, and professional and facility licensing data among federal, state, local and private entities. The Council will also advise AHCA regarding improvements to the comprehensive health information system for purposes of public health, policy analysis, and transparency of consumer health care information.

The bill specifies that the Council's duties and responsibilities will include developing a plan for the coordination of health-related data across federal, state, and local government and private-sector

entities and a review process to ensure cooperative planning among agencies that collect or maintain health-related data.

According to AHCA, the change in Council name will increase awareness among consumers and other interested parties regarding the Council's mission to advise AHCA regarding consumer health information.

In s. 408.05 (3)(l), F.S., AHCA is directed to develop, in conjunction with the Council, a long-range plan for public reporting to allow consumers to compare health care services, beginning with the release of patient charges, infection rates, mortality rates, complication rates and data on health plans by the dates specified. The Council's role is to advise AHCA on the method and format for public disclosure.

The specification of Council duties clarifies the Council's role and creates consistency with the current responsibilities of AHCA and new responsibilities related to the Florida Health Information Network.

Florida Health Information Network

The PCB authorizes the Agency for Health Care Administration (AHCA) and the State Center for Health Statistics to support the development of the Florida Health Information Network, as recommended by the Governor's Health Information Infrastructure Advisory Board (Board). These support activities include developing the network in incremental steps through the initiation of pilot projects, integrating health data collected and maintained by state agencies, and providing technical assistance to pilot projects and other stakeholders participating in the development of the Florida Health Information Network.

The bill codifies the activities related to the grant funding of the Florida Health Information Network. It adds responsibilities related to the integration and transfer of state data sets to the Florida Health Information Network.

The bill authorizes AHCA to continue to support the development of the Florida Health Information Network after the advisory Board expires in June 2007.

Policy Analysis

The PCB changes the name of the State Center for Health Statistics to the Florida Center for Health Information and Policy Analysis (Center). The bill provides that the Center shall include health-related data and statistics in the development of the comprehensive health information system and shall produce health information and statistics for the development of policy recommendations.

According to AHCA, the bill changes the title and description of responsibilities in order to direct the Center to perform policy analysis and develop policy recommendations. It broadens the purpose of the comprehensive health information system to include the development of public policy and expands the mission of the Center.

CURRENT SITUATION

Public Reporting

The Agency for Health Care Administration (AHCA) currently publishes data for public use on its consumer websites. In addition to the AHCA's central website (www.ahca@myflorida.com), AHCA publishes data on www.FloridaHealthStat.com, www.FloridaCompareCare.gov and www.MyFloridaRx.com.

The data made available on these consumer websites includes volume of cases, length-of-stay, and charges at each health care facility for groups of related diagnoses and procedures. The published data

is adjusted for severity of illness or condition. Date for calendar year 2004 is currently available in an interactive format where the user selects the type of data to be viewed based on a menu of options (www.ahca@myflorida.com/ www.floridahealthstat.com).

As of November 2005, AHCA has released, via website, the hospital readmission rates, complication rates, mortality rates, and infection rates (www.CompareCare.gov). In coordination with the Attorney General's Office, retail prices for select prescription drugs have been published since June 2005 through a searchable consumer website (www.MyFloridaRx.com).

AHCA uses the methodology developed by the Federal Agency for Healthcare Research and Quality to produce comparative consumer indicators. Licensed hospitals and ambulatory surgical centers report patient data that is used to develop the indicators.[1]

Pursuant to 59E-7, F.A.C., beginning in 2007 AHCA will require hospitals to report whether any secondary diagnosis contained in the records submitted to AHCA was present at admission. The additional admission data will enable the AHCA to expand and enhance reportable information on infection rates and complication rates.

The current requirements for public reporting in ss. 408.05 (3)(l) & 408.062(1)(j), F.S., use the terms "performance outcome data" or "performance outcome indicators." There are specific references to the publication of mortality rates, complication rates and infection rates in s. 408.05 (3)(l), F.S.

State Comprehensive Health Information System Advisory Council

The State Comprehensive Health Information System Advisory Council was established by s. 408.05 (8), F.S. to advise the Agency for Health Care Administration (AHCA) regarding the collection and dissemination of health information and make recommendations for improvements. The Council consists of 13 members with 10 members appointed by the Secretary of Health Care Administration, one member appointed by the Governor, one member appointed by the Chief Financial Officer, and one member appointed by the Commissioner of Education. Members are appointed for a term of four years.

Current section 408.05 (3)(l), F.S., directs AHCA to develop, in conjunction with the Council, a long-range plan for public reporting to allow consumers to compare health care services, beginning with the release of patient charges, infection rates, mortality rates, complications rates and information on health plans by the dates specified. The Council advises AHCA on the method and format for public disclosure.

Florida Health Information Network

Existing section 408.062(5), F.S., requires the Agency for Health Care Administration (AHCA) to develop a strategic plan for the adoption and use of electronic health records. AHCA is authorized to develop rules to facilitate the functionality and protect the confidentiality of electronic health records.

AHCA provides staff support to the Governor's Health Information Infrastructure Advisory Board which was established by Executive Order 04-93 in May of 2004. The Advisory Board advises and supports AHCA as it develops and implements a strategy for the adoption and use of electronic health records and creates a plan to promote the development and implementation of a Florida health information infrastructure. Under current law, the Board may continue to operate until June of 2007.

AHCA received an appropriation in fiscal year 2005-2006 for the Florida Health Information Network to be used to provide grant funding of local and regional health information exchange pilot projects.

[1] Data reported to AHCA is specified in 59B-9.010 through 59B-9.023, F.A.C. and 59E-7.011 through 59E-7.016, F.A.C. as authorized in s. 408.061, F.S.

Policy Analysis

Currently, the State Center for Health Statistics is authorized to produce publications on topical health policy issues in s. 408.05 (5)(a), F.S., although there is no specific requirement that AHCA perform public policy analysis or develop policy recommendations in this section. AHCA is required to report certain research studies in s. 408.062, F.S., including a report on health expenditures and a study of emergency department utilization and costs.

C. SECTION DIRECTORY:

Section 1. – Provides for a name citation as the, "Coordinated Health Care information Act."

Section 2. – Provides intent for the act. The purpose of the act is to provide for better coordination of health information for purposes of public health, policy analysis, and transparency of consumer health information.

Section 3. – Amends ss. 408.42 & 408.05, F.S., to change the title of the State Center for Health Statistics to Florida Center for Health Information and Policy Analysis. The act changes a number of provisions in current statute to better coordinate health information. Some of the changes made include:

- Specifies that the State Center for Health Statistics's role is to identify the best available data sources and coordinate the compilation of health-related data and statistics;
- Renames the State Comprehensive Health Information System Advisory Council to the State Consumer Health Information and Policy Advisory Council;
- Specifies duties and responsibility of the Council;
- Authorizes the Agency for Health Care Administration (AHCA) to manage and monitor grants to advance the Florida Health Information network; and
- Requires AHCA to oversee and manage data received from other state agencies.

Section 4. – Amends s. 408.061, F.S., to specify data be submitted by health care providers pursuant to the section may include their associations with professional organizations and their specialty board affiliations.

Section 5. – Amends s. 408.062(1)(h), F.S., to: increase the number of frequently prescribed medicines that will be posted on AHCA's website October 1, 2006 from 50 medicines to 100 medicines; require that performance indicators will be made available on AHCA's website, and that AHCA will submit an annual report on healthcare quality measures; and to provide that the required cesarean section report will be published periodically instead of annually on AHCA's website.

Section 6. – Amends s. 20.42, F.S., to change the name of the State Center for Health Statistics to the Florida Center for Health Statistics.

Section 7 through section 11. – Amends ss. 381.001, 395.602, 395.6025, 408.07, & 408.18, F.S., to provide a cross reference to the renamed Florida Center for Health Information and Policy Analysis.

Section 12. – Provides that the bill will take effect upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Agency for Health Care Administration has sufficient rulemaking authority to implement the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to health care information; providing a short title; providing purpose; amending s. 408.05, F.S.; renaming the State Center for Health Statistics; revising criteria for collection and use of certain health-related data; providing responsibilities of the Agency for Health Care Administration; providing for agency consultation with the State Consumer Health Information and Policy Advisory Council for the dissemination of certain consumer information; requiring the Florida Center for Health Information and Policy Analysis to provide certain technical assistance services; authorizing the agency to monitor certain grants; removing a provision relating to scope and application of provider data reporting; removing a provision that establishes the Comprehensive Health Information System Trust Fund as the repository of certain funds; renaming the State Comprehensive Health Information System Advisory Council; providing for duties and responsibilities of the State Consumer Health Information and Policy Advisory Council; providing for membership, terms, officers, and meetings; amending s. 408.061, F.S.; providing for health care providers to submit additional data to the agency; correcting a reference; amending s. 408.062, F.S.; revising provisions relating to availability of specified information on the agency's Internet website; requiring a report; removing an obsolete provision; amending ss. 20.42, 381.001, 395.602, 395.6025, 408.07, and 408.18, F.S.; conforming references to changes made by the act; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. This act may be cited as the "Coordinated Health Care Information and Transparency Act of 2006."

Section 2. The purpose of this act is to provide better coordination of health information for purposes of public health, policy analysis, and transparency of consumer health care information.

Section 3. Section 408.05, Florida Statutes, is amended to read:

408.05 Florida ~~State~~ Center for Health Information and Policy Analysis ~~Statistics~~.--

(1) ESTABLISHMENT.--The agency shall establish a Florida ~~State~~ Center for Health Information and Policy Analysis ~~Statistics~~. The center shall establish a comprehensive health information system to provide for the collection, compilation, coordination, analysis, indexing, dissemination, and utilization of both purposefully collected and extant health-related data and statistics. The center shall be staffed with public health experts, biostatisticians, information system analysts, health policy experts, economists, and other staff necessary to carry out its functions.

(2) HEALTH-RELATED DATA ~~STATISTICS~~.--The comprehensive health information system operated by the Florida ~~State~~ Center for Health Information and Policy Analysis ~~Statistics~~ shall identify the best available data sources and coordinate the compilation of extant health-related data and statistics and purposefully collect data on:

(a) The extent and nature of illness and disability of the state population, including life expectancy, the incidence of various acute and chronic illnesses, and infant and maternal morbidity and mortality.

(b) The impact of illness and disability of the state population on the state economy and on other aspects of the well-being of the people in this state.

(c) Environmental, social, and other health hazards.

(d) Health knowledge and practices of the people in this state and determinants of health and nutritional practices and status.

(e) Health resources, including physicians, dentists, nurses, and other health professionals, by specialty and type of practice and acute, long-term care and other institutional care facility supplies and specific services provided by hospitals, nursing homes, home health agencies, and other health care facilities.

(f) Utilization of health care by type of provider.

(g) Health care costs and financing, including trends in health care prices and costs, the sources of payment for health care services, and federal, state, and local expenditures for health care.

(h) Family formation, growth, and dissolution.

(i) The extent of public and private health insurance coverage in this state.

(j) The quality of care provided by various health care providers.

(3) COMPREHENSIVE HEALTH INFORMATION SYSTEM.--In order to produce comparable and uniform health information and statistics

for the development of policy recommendations, the agency shall perform the following functions:

(a) Coordinate the activities of state agencies involved in the design and implementation of the comprehensive health information system.

(b) Undertake research, development, and evaluation respecting the comprehensive health information system.

(c) Review the statistical activities of state agencies to ensure ~~the Department of Health to assure~~ that they are consistent with the comprehensive health information system.

(d) Develop written agreements with local, state, and federal agencies for the sharing of health-care-related data or using the facilities and services of such agencies. State agencies, local health councils, and other agencies under state contract ~~with the Department of Health~~ shall assist the center in obtaining, compiling, and transferring health-care-related data maintained by state and local agencies. Written agreements must specify the types, methods, and periodicity of data exchanges and specify the types of data that will be transferred to the center.

(e) The agency shall establish by rule the types of data collected, compiled, processed, used, or shared. Decisions regarding center data sets should be made based on consultation with the State Consumer ~~Comprehensive~~ Health Information and Policy ~~System~~ Advisory Council and other public and private users regarding the types of data which should be collected and their uses.

(f) The center shall establish standardized means for collecting health information and statistics under laws and rules administered by the agency.

(g) Establish minimum health-care-related data sets which are necessary on a continuing basis to fulfill the collection requirements of the center and which shall be used by state agencies in collecting and compiling health-care-related data. The agency shall periodically review ongoing health care data collections of the Department of Health and other state agencies to determine if the collections are being conducted in accordance with the established minimum sets of data.

(h) Establish advisory standards to ensure ~~assure~~ the quality of health statistical and epidemiological data collection, processing, and analysis by local, state, and private organizations.

(i) Prescribe standards for the publication of health-care-related data reported pursuant to this section which ensure the reporting of accurate, valid, reliable, complete, and comparable data. Such standards should include advisory warnings to users of the data regarding the status and quality of any data reported by or available from the center.

(j) Prescribe standards for the maintenance and preservation of the center's data. This should include methods for archiving data, retrieval of archived data, and data editing and verification.

(k) Ensure that strict quality control measures are maintained for the dissemination of data through publications, studies, or user requests.

(l) Develop, in conjunction with the State Consumer ~~Comprehensive~~ Health Information and Policy ~~System~~ Advisory Council, and implement a long-range plan for making available health care quality measures ~~performance outcome~~ and financial

data that will allow consumers to compare health care services. The health care quality measures ~~performance outcomes~~ and financial data the agency must make available shall include, but is not limited to, pharmaceuticals, physicians, health care facilities, and health plans and managed care entities. The agency shall submit the initial plan to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 1, 2006, and shall update the plan and report on the status of its implementation annually thereafter. The agency shall also make the plan and status report available to the public on its Internet website. As part of the plan, the agency shall identify the process and timeframes for implementation, any barriers to implementation, and recommendations of changes in the law that may be enacted by the Legislature to eliminate the barriers. As preliminary elements of the plan, the agency shall:

1. Make available health care quality measures which shall include, but not be limited to, process measures, patient safety measures, inpatient quality indicators, preventable adverse drug events, performance measures, ~~outcome~~ and patient charge data collected from health care facilities pursuant to s. 408.061(1)(a) and (2). The agency shall determine which conditions, ~~and~~ procedures, health care quality measures ~~performance outcomes~~, and patient charge data to disclose based upon input from the council. When determining which conditions and procedures are to be disclosed, the council and the agency shall consider variation in costs, variation in outcomes, and magnitude of variations and other relevant information. When

determining which health care quality measures ~~performance outcomes~~ to disclose, the agency:

a. Shall consider such factors as volume of cases; average patient charges; average length of stay; complication rates; mortality rates; and infection rates, among others, which shall be adjusted for case mix and severity, if applicable.

b. May consider such additional measures that are adopted by the Centers for Medicare and Medicaid Studies, National Quality Forum, the Joint Commission on Accreditation of Healthcare Organizations, the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, or a similar national entity that establishes standards to measure the performance of health care providers, or by other states.

When determining which patient charge data to disclose, the agency shall consider such measures as average charge, average net revenue per adjusted patient day, average cost per adjusted patient day, and average cost per admission, among others.

2. Make available performance measures, benefit design, and premium cost data from health plans licensed pursuant to chapter 627 or chapter 641. The agency shall determine which health care quality measures ~~performance outcome~~ and member and subscriber cost data to disclose, based upon input from the council. When determining which data to disclose, the agency shall consider information that may be required by either individual or group purchasers to assess the value of the product, which may include membership satisfaction, quality of care, current enrollment or membership, coverage areas, accreditation status, premium costs, plan costs, premium increases, range of benefits, copayments and

deductibles, accuracy and speed of claims payment, credentials of physicians, number of providers, names of network providers, and hospitals in the network. Health plans shall make available to the agency any such data or information that is not currently reported to the agency or the office.

3. Determine the method and format for public disclosure of data reported pursuant to this paragraph. The agency shall make its determination based upon input from the Consumer ~~Comprehensive~~ Health Information and Policy ~~System~~ Advisory Council. At a minimum, the data shall be made available on the agency's Internet website in a manner that allows consumers to conduct an interactive search that allows them to view and compare the information for specific providers. The website must include such additional information as is determined necessary to ensure that the website enhances informed decisionmaking among consumers and health care purchasers, which shall include, at a minimum, appropriate guidance on how to use the data and an explanation of why the data may vary from provider to provider. The data specified in subparagraph 1. shall be released no later than January 1, 2006, for the reporting of infection rates, and no later than October 1, 2005, for mortality rates and complication rates. The data specified in subparagraph 2. shall be released no later than October 1, 2006.

(4) TECHNICAL ASSISTANCE.--

(a) The center shall provide technical assistance to persons or organizations engaged in health planning activities in the effective use of statistics collected and compiled by the center. The center shall also provide the following additional technical assistance services:

1.~~(a)~~ Establish procedures identifying the circumstances under which, the places at which, the persons from whom, and the methods by which a person may secure data from the center, including procedures governing requests, the ordering of requests, timeframes for handling requests, and other procedures necessary to facilitate the use of the center's data. To the extent possible, the center should provide current data timely in response to requests from public or private agencies.

2.~~(b)~~ Provide assistance to data sources and users in the areas of database design, survey design, sampling procedures, statistical interpretation, and data access to promote improved health-care-related data sets.

3.~~(c)~~ Identify health care data gaps and provide technical assistance to ~~seek cooperative agreements with~~ other public or private organizations for meeting documented health care data needs.

4.~~(d)~~ Assist other organizations in developing statistical abstracts of their data sets that could be used by the center.

5.~~(e)~~ Provide statistical support to state agencies with regard to the use of databases maintained by the center.

6.~~(f)~~ To the extent possible, respond to multiple requests for information not currently collected by the center or available from other sources by initiating data collection.

7.~~(g)~~ Maintain detailed information on data maintained by other local, state, federal, and private agencies in order to advise those who use the center of potential sources of data which are requested but which are not available from the center.

8. ~~(h)~~ Respond to requests for data which are not available in published form by initiating special computer runs on data sets available to the center.

9. Be responsible for monitoring innovations in health information technology, informatics, and health information exchange and maintain a repository of technical resources for support of the Florida Health Information Network.

(b) The agency shall have the authority to administer, manage, and monitor grants to not-for-profit organizations, regional health information organizations, public health departments, or state agencies that submit proposals for planning, implementation, or training projects to advance the purposes of the Florida Health Information Network. All grant contracts shall be evaluated to ensure the effective outcome of the health information projects.

(c) The agency shall initiate, oversee, manage, and evaluate the integration of health care data from each state agency that collects, stores, and reports on health care issues and shall make that data available to health care practitioners through the Florida Health Information Network.

(5) PUBLICATIONS; REPORTS; SPECIAL STUDIES.--The center shall provide for the widespread dissemination of data which it collects and analyzes. The center shall have the following publication, reporting, and special study functions:

(a) The center shall publish and make available periodically to agencies and individuals health statistics publications of general interest, including health plan consumer reports and health maintenance organization member satisfaction surveys ~~HMO report cards~~; publications providing health

statistics on topical health policy issues; publications that provide health status profiles of the people in this state; and other topical health statistics publications.

(b) The center shall publish, make available, and disseminate, promptly and as widely as practicable, the results of special health surveys, health care research, and health care evaluations conducted or supported under this section. Any publication by the center must include a statement of the limitations on the quality, accuracy, and completeness of the data.

(c) The center shall provide indexing, abstracting, translation, publication, and other services leading to a more effective and timely dissemination of health care statistics.

(d) The center shall be responsible for publishing and disseminating an annual report on the center's activities.

(e) The center shall be responsible, to the extent resources are available, for conducting a variety of special studies and surveys to expand the health care information and statistics available for health policy analyses, particularly for the review of public policy issues. The center shall develop a process by which users of the center's data are periodically surveyed regarding critical data needs and the results of the survey considered in determining which special surveys or studies will be conducted. The center shall select problems in health care for research, policy analyses, or special data collections on the basis of their local, regional, or state importance; the unique potential for definitive research on the problem; and opportunities for application of the study findings.

~~(6) PROVIDER DATA REPORTING.--This section does not confer on the agency the power to demand or require that a health care provider or professional furnish information, records of interviews, written reports, statements, notes, memoranda, or data other than as expressly required by law.~~

(6)~~(7)~~ BUDGET; FEES~~; TRUST FUND~~.--

(a) The Legislature intends that funding for the Florida ~~State~~ Center for Health Information and Policy Analysis ~~Statistics~~ be appropriated from the General Revenue Fund.

(b) The Florida ~~State~~ Center for Health Information and Policy Analysis ~~Statistics~~ may apply for and receive and accept grants, gifts, and other payments, including property and services, from any governmental or other public or private entity or person and make arrangements as to the use of same, including the undertaking of special studies and other projects relating to health-care-related topics. Funds obtained pursuant to this paragraph may not be used to offset annual appropriations from the General Revenue Fund.

(c) The center may charge such reasonable fees for services as the agency prescribes by rule. The established fees may not exceed the reasonable cost for such services. Fees collected may not be used to offset annual appropriations from the General Revenue Fund.

~~(d) The agency shall establish a Comprehensive Health Information System Trust Fund as the repository of all funds appropriated to, and fees and grants collected for, services of the State Center for Health Statistics. Any funds, other than funds appropriated to the center from the General Revenue Fund, which are raised or collected by the agency for the operation of~~

~~the center and which are not needed to meet the expenses of the center for its current fiscal year shall be available to the agency in succeeding years.~~

(7) ~~(8)~~ STATE CONSUMER ~~COMPREHENSIVE~~ HEALTH INFORMATION AND POLICY ~~SYSTEM~~ ADVISORY COUNCIL.--

(a) There is established in the agency the State Consumer ~~Comprehensive~~ Health Information and Policy ~~System~~ Advisory Council to assist the center in reviewing the comprehensive health information system, including the identification, collection, standardization, sharing, and coordination of health-related data, fraud and abuse data, and professional and facility licensing data among federal, state, local, and private entities and to recommend improvements for purposes of public health, policy analysis, and transparency of consumer health care information ~~such system~~. The council shall consist of the following members:

1. An employee of the Executive Office of the Governor, to be appointed by the Governor.

2. An employee of the Office of Insurance Regulation, to be appointed by the director of the office.

3. An employee of the Department of Education, to be appointed by the Commissioner of Education.

4. Ten persons, to be appointed by the Secretary of Health Care Administration, representing other state and local agencies, state universities, business and health ~~the Florida Association of Business/Health~~ coalitions, local health councils, professional health-care-related associations, consumers, and purchasers.

(b) Each member of the council shall be appointed to serve for a term of 2 ~~4~~ years from the date of appointment, except that a vacancy shall be filled by appointment for the remainder of the term. ~~and except that:~~

~~1. Three of the members initially appointed by the Director of Health Care Administration shall each be appointed for a term of 3 years.~~

~~2. Two of the members initially appointed by the Director of Health Care Administration shall each be appointed for a term of 2 years.~~

~~3. Two of the members initially appointed by the Director of Health Care Administration shall each be appointed for a term of 1 year.~~

(c) The council may meet at the call of its chair, at the request of the agency ~~department~~, or at the request of a majority of its membership, but the council must meet at least quarterly.

(d) Members shall elect a chair and vice chair annually.

(e) A majority of the members constitutes a quorum, and the affirmative vote of a majority of a quorum is necessary to take action.

(f) The council shall maintain minutes of each meeting and shall make such minutes available to any person.

(g) Members of the council shall serve without compensation but shall be entitled to receive reimbursement for per diem and travel expenses as provided in s. 112.061.

(h) The council's duties and responsibilities include, but are not limited to, the following:

1. To develop a mission statement, goals, and a plan of action based on the guiding principles specified in s. 282.3032

for the identification, collection, standardization, sharing, and coordination of health-related data across federal, state, and local government and private-sector entities.

2. To develop a review process to ensure cooperative planning among agencies that collect or maintain health-related data.

3. To create ad hoc issue-oriented technical workgroups on an as-needed basis to make recommendations to the council.

(8) ~~(9)~~ APPLICATION TO OTHER AGENCIES.--Nothing in this section shall limit, restrict, affect, or control the collection, analysis, release, or publication of data by any state agency pursuant to its statutory authority, duties, or responsibilities.

Section 4. Paragraph (b) of subsection (1) and subsection (10) of section 408.061, Florida Statutes, are amended to read:

408.061 Data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.--

(1) The agency shall require the submission by health care facilities, health care providers, and health insurers of data necessary to carry out the agency's duties. Specifications for data to be collected under this section shall be developed by the agency with the assistance of technical advisory panels including representatives of affected entities, consumers, purchasers, and such other interested parties as may be determined by the agency.

(b) Data to be submitted by health care providers may include, but are not limited to: professional organization and specialty board affiliations, Medicare and Medicaid participation, types of services offered to patients, amount of revenue and expenses of the health care provider, and such other

data which are reasonably necessary to study utilization patterns. Data submitted shall be certified by the appropriate duly authorized representative or employee of the health care provider that the information submitted is true and accurate.

(10) The agency shall be the primary source for collection and dissemination of health care data. No other agency of state government may gather data from a health care provider licensed or regulated under this chapter without first determining if the data is currently being collected by the agency and affirmatively demonstrating that it would be more cost-effective for an agency of state government other than the agency to gather the health care data. The secretary ~~director~~ shall ensure that health care data collected by the divisions within the agency is coordinated. It is the express intent of the Legislature that all health care data be collected by a single source within the agency and that other divisions within the agency, and all other agencies of state government, obtain data for analysis, regulation, and public dissemination purposes from that single source. Confidential information may be released to other governmental entities or to parties contracting with the agency to perform agency duties or functions as needed in connection with the performance of the duties of the receiving entity. The receiving entity or party shall retain the confidentiality of such information as provided for herein.

Section 5. Paragraphs (h) and (j) of subsection (1) and subsection (2) of section 408.062, Florida Statutes, are amended to read:

408.062 Research, analyses, studies, and reports.--

(1) The agency shall conduct research, analyses, and studies relating to health care costs and access to and quality of health care services as access and quality are affected by changes in health care costs. Such research, analyses, and studies shall include, but not be limited to:

(h) The collection of a statistically valid sample of data on the retail prices charged by pharmacies for the 100 ~~50~~ most frequently prescribed medicines from any pharmacy licensed by this state as a special study authorized by the Legislature to be performed by the agency quarterly. If the drug is available generically, price data shall be reported for the generic drug and price data of a brand-named drug for which the generic drug is the equivalent shall be reported. The agency shall make available on its Internet website for each pharmacy, no later than October 1, 2006 ~~2005~~, drug prices for a 30-day supply at a standard dose. The data collected shall be reported for each drug by pharmacy and by metropolitan statistical area or region and updated quarterly.

(j) The making available on its Internet website beginning no later than October 1, 2004, and in a hard-copy format upon request, of patient charge, volumes, length of stay, and performance ~~outcome~~ indicators collected from health care facilities pursuant to s. 408.061(1)(a) for specific medical conditions, surgeries, and procedures provided in inpatient and outpatient facilities as determined by the agency. In making the determination of specific medical conditions, surgeries, and procedures to include, the agency shall consider such factors as volume, severity of the illness, urgency of admission, individual and societal costs, and whether the condition is acute or

chronic. Performance ~~outcome~~ indicators shall be risk adjusted or severity adjusted, as applicable, using nationally recognized risk adjustment methodologies or software consistent with the standards of the Agency for Healthcare Research and Quality and as selected by the agency. The website shall also provide an interactive search that allows consumers to view and compare the information for specific facilities, a map that allows consumers to select a county or region, definitions of all of the data, descriptions of each procedure, and an explanation about why the data may differ from facility to facility. Such public data shall be updated quarterly. The agency shall submit an annual status report on the collection of data and publication of health care quality measures ~~performance outcome indicators~~ to the Governor, the Speaker of the House of Representatives, the President of the Senate, and the substantive legislative committees with the first status report due January 1, 2005.

(2) The agency may assess annually the caesarean section rate in Florida hospitals using the analysis methodology that the agency determines most appropriate. The data from this assessment shall be published periodically on the agency's Internet website. ~~To assist the agency in determining the impact of this chapter on Florida hospitals' caesarean section rates, each provider hospital, as defined in s. 383.336, shall notify the agency of the date of implementation of the practice parameters and the date of the first meeting of the hospital peer review board created pursuant to this chapter. The agency shall use these dates in monitoring any change in provider hospital caesarean section rates. An annual report based on this monitoring and assessment shall be submitted to the Governor, the Speaker of the~~

~~House of Representatives, and the President of the Senate by the agency, with the first annual report due January 1, 1993.~~

Section 6. Subsection (3) of section 20.42, Florida Statutes, is amended to read:

20.42 Agency for Health Care Administration.--

(3) The department shall be the chief health policy and planning entity for the state. The department is responsible for health facility licensure, inspection, and regulatory enforcement; investigation of consumer complaints related to health care facilities and managed care plans; the implementation of the certificate of need program; the operation of the Florida ~~State~~ Center for Health Information and Policy Analysis ~~Statistics~~; the administration of the Medicaid program; the administration of the contracts with the Florida Healthy Kids Corporation; the certification of health maintenance organizations and prepaid health clinics as set forth in part III of chapter 641; and any other duties prescribed by statute or agreement.

Section 7. Subsection (3) of section 381.001, Florida Statutes, is amended to read:

381.001 Legislative intent; public health system.--

(3) It is, furthermore, the intent of the Legislature that the public health system include comprehensive planning, data collection, technical support, and health resource development functions. These functions include, but are not limited to, state laboratory and pharmacy services, the state vital statistics system, the Florida ~~State~~ Center for Health Information and Policy Analysis ~~Statistics~~, emergency medical services coordination and support, and recruitment, retention, and

development of preventive and primary health care professionals and managers.

Section 8. Paragraph (e) of subsection (2) of section 395.602, Florida Statutes, is amended to read:

395.602 Rural hospitals.--

(2) DEFINITIONS.--As used in this part:

(e) "Rural hospital" means an acute care hospital licensed under this chapter, having 100 or fewer licensed beds and an emergency room, which is:

1. The sole provider within a county with a population density of no greater than 100 persons per square mile;

2. An acute care hospital, in a county with a population density of no greater than 100 persons per square mile, which is at least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from any other acute care hospital within the same county;

3. A hospital supported by a tax district or subdistrict whose boundaries encompass a population of 100 persons or fewer per square mile;

4. A hospital in a constitutional charter county with a population of over 1 million persons that has imposed a local option health service tax pursuant to law and in an area that was directly impacted by a catastrophic event on August 24, 1992, for which the Governor of Florida declared a state of emergency pursuant to chapter 125, and has 120 beds or less that serves an agricultural community with an emergency room utilization of no less than 20,000 visits and a Medicaid inpatient utilization rate greater than 15 percent;

5. A hospital with a service area that has a population of 100 persons or fewer per square mile. As used in this subparagraph, the term "service area" means the fewest number of zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database in the Florida ~~State~~ Center for Health Information and Policy Analysis ~~Statistics~~ at the Agency for Health Care Administration; or

6. A hospital designated as a critical access hospital, as defined in s. 408.07(15).

Population densities used in this paragraph must be based upon the most recently completed United States census. A hospital that received funds under s. 409.9116 for a quarter beginning no later than July 1, 2002, is deemed to have been and shall continue to be a rural hospital from that date through June 30, 2012, if the hospital continues to have 100 or fewer licensed beds and an emergency room, or meets the criteria of subparagraph 4. An acute care hospital that has not previously been designated as a rural hospital and that meets the criteria of this paragraph shall be granted such designation upon application, including supporting documentation to the Agency for Health Care Administration.

Section 9. Section 395.6025, Florida Statutes, is amended to read:

395.6025 Rural hospital replacement facilities.--Notwithstanding the provisions of s. 408.036, a hospital defined as a statutory rural hospital in accordance with s. 395.602, or a not-for-profit operator of rural hospitals, is

not required to obtain a certificate of need for the construction of a new hospital located in a county with a population of at least 15,000 but no more than 18,000 and a density of less than 30 persons per square mile, or a replacement facility, provided that the replacement, or new, facility is located within 10 miles of the site of the currently licensed rural hospital and within the current primary service area. As used in this section, the term "service area" means the fewest number of zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database in the Florida ~~State~~ Center for Health Information and Policy Analysis ~~Statistics~~ at the Agency for Health Care Administration.

Section 10. Paragraph (d) of subsection (43) of section 408.07, Florida Statutes, is amended to read:

408.07 Definitions.--As used in this chapter, with the exception of ss. 408.031-408.045, the term:

(43) "Rural hospital" means an acute care hospital licensed under chapter 395, having 100 or fewer licensed beds and an emergency room, and which is:

(d) A hospital with a service area that has a population of 100 persons or fewer per square mile. As used in this paragraph, the term "service area" means the fewest number of zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database in the Florida ~~State~~ Center for Health Information and Policy Analysis ~~Statistics~~ at the Agency for Health Care Administration; or

Population densities used in this subsection must be based upon the most recently completed United States census. A hospital that received funds under s. 409.9116 for a quarter beginning no later than July 1, 2002, is deemed to have been and shall continue to be a rural hospital from that date through June 30, 2012, if the hospital continues to have 100 or fewer licensed beds and an emergency room, or meets the criteria of s. 395.602(2)(e)4. An acute care hospital that has not previously been designated as a rural hospital and that meets the criteria of this subsection shall be granted such designation upon application, including supporting documentation, to the Agency for Health Care Administration.

Section 11. Paragraph (a) of subsection (4) of section 408.18, Florida Statutes, is amended to read:

408.18 Health Care Community Antitrust Guidance Act; antitrust no-action letter; market-information collection and education.--

(4)(a) Members of the health care community who seek antitrust guidance may request a review of their proposed business activity by the Attorney General's office. In conducting its review, the Attorney General's office may seek whatever documentation, data, or other material it deems necessary from the Agency for Health Care Administration, the Florida ~~State~~ Center for Health Information and Policy Analysis ~~Statistics~~, and the Office of Insurance Regulation of the Financial Services Commission.

Section 12. This act shall take effect upon becoming a law.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **PCB HCR 06-01**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Garcia offered the following:

Amendment (with directory and title amendments)

Remove line(s) 162-165 and insert:

1. Make available health care quality measures that include, but are not limited to, process measures, patient-safety indicators, inpatient quality indicators, performance measures, ~~performance outcome~~ and patient charge data

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 2 (for drafter's use only)

Bill No. **PCB HCR 06-01**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Garcia offered the following:

Amendment (with directory and title amendments)

Remove line(s) 262-278 and insert:

9. Monitor innovations in health information technology, informatics, and the exchange of health information and maintain a repository of technical resources to support the development of a Florida health information network.

(b) Administer, manage, and monitor grants to not-for-profit organizations, regional health information organizations, public health departments or state agencies that submit proposals for planning, implementation, or training projects to advance the development of a Florida health information network. Any grant contract shall be evaluated to ensure the effective outcome of the health information project.

(c) Initiate, oversee, manage, and evaluate the integration of health care data from each state agency that collects, stores, and reports on health care issues, and make

that data available to any health care practitioner through the Florida health information network.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 3 (for drafter's use only)

Bill No. **PCB HCR 06-01**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Garcia offered the following:

Amendment (with directory and title amendments)

Remove line(s) 316-320 and insert:

(6) PROVIDER DATA REPORTING.--This section does not confer on the agency the power to demand or require that a health care provider or professional furnish information, records of interviews, written reports, statements, notes, memoranda, or data other than as expressly required by law.

========== T I T L E A M E N D M E N T ==========

Remove line(s) 13-14 and insert:

monitor certain grants; removing

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 4 (for drafter's use only)

Bill No. **PCB HCR 06-01**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Garcia offered the following:

Amendment (with directory and title amendments)

Remove line(s) 374-376 and insert:

for a term of 2 ~~4~~ years following ~~from~~ the date of appointment, except the term of appointment shall end 3 years following the date of appointment for members appointed in 2003, 2004, and 2005. ~~that~~ A vacancy shall be filled by appointment for the remainder of the term, and each appointing authority retains the right to reappoint members whose terms of appointment have expired. ~~and except that:~~

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 5 (for drafter's use only)

Bill No. **PCB HCR 06-01**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Garcia offered the following:

Amendment (with directory and title amendments)

Between line(s) 518-519 insert:

(5) The agency shall develop and implement a strategy for the adoption and use of electronic health records, including the development of an electronic health information network for the sharing of electronic health records among health care facilities, health care providers, and health insurers. The agency may develop rules to facilitate the functionality and protect the confidentiality of electronic health records. The agency shall report to the Governor, the Speaker of the House of Representatives, and the President of the Senate on legislative recommendations to protect the confidentiality of electronic health records.

========== D I R E C T O R Y A M E N D M E N T ==========

Remove line(s) 455-457 and insert:

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Section 5. Paragraphs (h) and (j) of subsection (1), and subsections (2) and (5) of section 408.062, Florida Statutes, are amended to read:

========== T I T L E A M E N D M E N T ==========

Remove line(s) 27 and insert:

provision; authorizing the agency to develop an electronic health information network; amending ss. 20.42, 381.001, 395.602, 395.6025,

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HCR 06-03 Clandestine Laboratory Contamination
SPONSOR(S): Health Care Regulation Committee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.: Health Care Regulation Committee		Hamrick	Mitchell
1)			
2)			
3)			
4)			
5)			

SUMMARY ANALYSIS

This proposed committee bill addresses the problem of harm to families with children who unknowingly rent or buy a house that was used as a methamphetamine lab. Currently, methamphetamine laboratories are seized by the Drug Enforcement Agency and/or the Florida Department of Law Enforcement and all hazardous ingredients and equipment is removed from the premises but nothing is done with the property. In Florida, there is no mechanism to determine whether a house (or residential property) was once a clandestine laboratory; no remediation is required to be done on the residential property; and there is no way to notify subsequent occupants of any health risks.

The bill establishes a notification process to advise the public of any health risks, a decontamination standard, and a remediation protocol. The bill requires a 'decontamination specialist', who is an employee or qualified contractor hired by the Department of Health, to determine if a clandestine lab is contaminated based on specified standards. The bill requires law enforcement personnel to post a notice on the residential property at the time they collect and remove evidence from an illegal lab site. The bill provides that a residential property may be quarantined by the Department of Health if the property was used as a clandestine laboratory. The quarantine is enforced by the Florida Department of Law Enforcement. The bill includes other provisions such as immunity liability for health-based civil actions, ability to petition a court to have a quarantine lifted, and provides the department the ability to file a lien.

Currently, the Department of Health has the authority to declare, enforce, modify, and abolish a quarantine placed on persons and premises as the circumstances indicate in order to protect the public from unsafe conditions that pose a threat to public health. Currently, it is the duty of every state and county attorney, sheriff, police officer, and other appropriate city and county officials to assist the Department of Health in enforcing the state health laws.

Fiscal Impact: According to the Department of Health, the bill is expected to have an estimated fiscal impact of $2.5 million dollars for the first year of implementation. However, the proposed strike-all amendment significantly decreases the fiscal impact to the Department of Health and alters the role of the department by transferring the assessment of decontamination to qualified independent contractors in the private sector.

The bill will take effect on July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government-The bill provides a mechanism that will prevent a person from unknowingly living in a former clandestine laboratory that has not been decontaminated.

Promote personal responsibility-The bill may encourage landlords to thoroughly screen potential renters or applicants and encourage them to look for signs of illegal drug activity.

B. EFFECT OF PROPOSED CHANGES:

The proposed committee bill provides that a residential property may be quarantined by the Department of Health if the property was used as a clandestine laboratory. The bill establishes a notification process to advise the public of any health risks, a decontamination standard, and a remediation protocol.

The bill:

- Requires law enforcement to post a notice on the residential property at the time they are collecting and removing evidence from a clandestine lab.
  - The notice must state: The property is quarantined and a clandestine lab found on the residential property; date of quarantine; name of agency posting the quarantine; statement specifying the hazards that may remain and exposure to the substances may be harmful and may pose a threat to public health and the environment; that it is unlawful for unauthorized persons to enter the contaminated property, and a statement explaining how to have the quarantine lifted; and that it is a second degree misdemeanor to remove the notice.
- Allows property owners to petition a court to have the quarantine lifted in the event they believe their property was wrongfully quarantined or has been decontaminated or demolished but the quarantine was not lifted.
- Requires law enforcement personnel to enforce a quarantine on a clandestine laboratory located in a residential property at the time they secure and remove evidence from said property.
- Requires a 'decontamination specialist', who is an employee or qualified contractor hired by the Department of Health, to determine if a clandestine lab is contaminated based on specified standards.
- Provides the department the authority to file a lien on residential property found to be contaminated to cover costs of testing.
- Provides immunity, with certain restrictions, from liability for health-based civil actions if the residential property owner decontaminates or opts to demolish the residential property.
- Provides residential property owners the option to demolish a home in lieu of decontamination with certain requirements.
- Requires the department to compile and maintain a list on the internet of 'clandestine laboratory cleanup specialists.'
- Provides the department authority to request law enforcement reports to assist in evaluating if a residential property is contaminated.
- Provides the Department of Health the authority to promulgate rules to:
  - Establish a 'certificate of fitness' that acts as documentation signifying that a home has been properly decontaminated;
  - Establish the standards for cleanup and testing of clandestine labs;
  - Create a uniform notice and letter; and
  - Specify the requirements of persons authorized to perform clandestine laboratory cleanup.

PRESENT SITUATION

Currently, methamphetamine laboratories are seized by the Drug Enforcement Agency (DEA) and/or the Florida Department of Law Enforcement (FDLE) and all hazardous ingredients and equipment are removed from the premises but nothing is done with the property or remaining contaminated materials. Families with children have been harmed by unknowingly renting or buying a house that was used as a methamphetamine lab due to the absence of decontamination requirements.[1] In 2004, 61 children were found at seized methamphetamine labs in Florida.[2] Currently in Florida, there is no mechanism to determine whether a house (or residential property) was once a clandestine laboratory; no remediation is required to be done on the residential property; and there is no way to notify subsequent occupants of any health risks. Law enforcement and/or special contract vendors simply remove all hazardous chemicals and lab items from a clandestine laboratory.

FEDERAL INITIATIVES

COPS Program Provides Federal Funding to States and Local Governments

In 1998, the Office of Community Oriented Policing Services (COPS) began the Methamphetamine Initiative program that provided $4.5 million to six US cities to implement anti-methamphetamine projects. In 2005, Florida received $832,116 from the COPS program to remove hazardous materials from 388 seized clandestine labs.

Removal and cleanup of hazardous materials seized at clandestine labs must meet the requirements of the Occupational Safety and Health Administration (OSHA), and the Environmental Protection Agency's Resource Conservation and Recovery Act regulations pertaining to the generation, storage, transport, and disposal of hazardous wastes in addition to any state or local requirements.[3] COPS funding does not extend to any level of cleanup relating to decontamination other than removal of remaining hazardous materials and manufacturing equipment.

According to the U.S. Department of Justice, the removal of hazardous materials from a seized clandestine lab is the responsibility of the state or local law enforcement agency that discovers the materials.[4] The state or local law enforcement agency may use the COPS funding to perform the removal themselves using qualified law enforcement or other qualified government personnel; use Drug Enforcement Administration hazardous waste management contractors; or use other qualified contractors. State and local law enforcement agencies may only use COPS grant funding to pay for hazardous waste removal, transportation, storage, and payment of hazardous waste disposal fees.[5]

COPS Program and El Paso Intelligence Center (EPIC)

In order to receive COPS funding for handling hazardous lab materials a DEA Form 612 also called "EPIC form" must be completed and forwarded to the El Paso Intelligence Center, which is the national repository of data concerning clandestine laboratory seizures. The data collected includes the location of the lab, estimated lab capacity, manufacturing process used, lab equipment found on the scene, name of chemist and clean-up personnel, weapons and/or explosives seized, quantity of drugs seized, and precursor agents/catalysts/solvents/reagents seized.[6]

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[1] Jerome, Richard. PEOPLE. "Home Toxic Home?" (August 8, 2005).
[2] Tseng, Nin-Hai. Orlando Sentinel. "Children fall by the wayside in meth-addicted homes." (September 11, 2005).
[3] See 29 CFR Part 1910.120, and Part 1200; 40 CRR Part 260.
[4] US Department of Justice, Office of Community Oriented Policing Services. Methamphetamine Initiative: Final Environmental Assessment. May 13, 2003.
[5] Ibid.
[6] See DEA Form 612 Instructions (Rev. 04/03)

Environmental Protection Agency Funding to State and Local Governments

The Environmental Protection Agency (EPA) makes funding available to state and local governments for the assessment and cleanup of meth lab sites through the Office of Brownfields Cleanup and Redevelopment via grants of up to $200,000 per site.[7] State and local governments may receive grants up to $1 million to be used for the capitalization of revolving loan funds; they may then make loans and sub-grants for the cleanup of methamphetamine lab sites.

FLORIDA INITATIVES

In 2003, the Office of Drug Control, Florida Department of Law Enforcement, and the federal Drug Enforcement Administration signed a resolution to jointly implement a statewide strategy to deal with clandestine methamphetamine laboratories in Florida. The purpose of the strategy is to combine efforts to combat the manufacturing and distribution of methamphetamines in Florida and improve the overall effectiveness and efficiency of law enforcement's response and investigations.

In 2005, the Florida Department of Children and Families (DCF) established the Northwest Florida Drug Endangered Children Work Group. Subsequently, they published the Northwest Florida Drug Endangered Children Multidisciplinary Protocol to provide law enforcement, DCF, social services, fire and medical services, and prosecutors a basis for the development of community specific procedures handling children where there has been drug production, trafficking, and abuse. DCF is required to remove children from homes in which they have suffered from neglect, abuse, and exposure to toxic and volatile environments.

In 2005 the Legislature passed HB 1347 that placed quantity and point of sale restrictions on over-the-counter cold medicines that contain ephedrine, pseudoephedrine or phenylpropanolamine. The bill also increased several penalty provisions that include making it a 1st degree felony for any child less than 16 years of age to be present while manufacturing methamphetamine.

In 2005, the Florida Office of Drug Control brought together a multi-agency group of experts in handling methamphetamine issues. The workgroup is in the process of creating a single source document called the Florida Statewide Methamphetamine Protocol that will assist federal, state, and local agencies in handling the criminal, environmental, sociological and economic issues that are characteristic of clandestine methamphetamine laboratories.

The Attorney General's Office in partnership with the Department of Health, Department of Children and Families, Office of Drug Control, Florida Department of Law Enforcement, and the Drug Enforcement Agency recently unveiled the Florida Alliance for Drug Endangered Children website (www.floridadec.org).

WHAT IS METHAMPHETAMINE?

Methamphetamine is a central nervous system stimulant commonly referred to as "meth." Its street names are numerous and include such terms as crank, speed, ice or crystal.[8] Meth is a derivative of amphetamine that dates back to the early 1900s. The drug became more widely used during World War II and eventually became widely available in tablet form.[9] Meth can be found and used in numerous forms, i.e., injected, smoked, inhaled, or taken orally. The 1970 Controlled Substances Act, made the production of injectable meth illegal. According to the Oregon Department of Human

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[7] U.S. Congress. House Committee on Energy and Commerce, Subcommittee on Energy and Hazardous Materials. 2005. "Testimony of Peter Murtha, Director Office of Criminal Enforcement, Forensics and Training Office of Enforcement and Compliance Assurance U.S. Environmental Protection Agency." 109th Congress.

[8] US Department of Justice, Office of Community Policing Services. Methamphetamine Fact Sheet. http://www.cops.usdoj.gov/mime/open.pdf?Item=1356 (February 3, 2006).

[9] US Department of Justice, Office of Community Policing Services. An Evaluation of the COPS Office Methamphetamine Initiative. http://www.cops.usdoj.gov/mime/open.pdf?Item=608 (February 3, 2006).

Services, methamphetamine is currently the illicit "drug of choice" due to its ease of manufacture, comparatively low cost, 12-hour half-life, and the euphoria, energy, and feelings of power, and sexual arousal that it produces.[10] A key ingredient of methamphetamine production is pseudoephedrine/ephedrine, which is commonly found in cold medicine.

According to a report by the State of North Carolina, clandestine[11] methamphetamine laboratories account for more than 90% of all U.S. illegal drug seizures in recent years.[12] In 2000 the Drug Abuse Warning Network, indicated that among club drugs, meth accounted for the largest share of emergency department mentions, and was especially problematic in the metropolitan areas of the western US. The DEA has estimated that the manufacturing or "cooking" of methamphetamine leaves behind 5 to 7 pounds of chemical waste for each pound of meth that is made.[13]

HEALTH RISKS ASSOCIATED WITH METHAMPHETAMINE MANUFACTURING

Toxic substances from the cooking process can permeate walls, floorboards, and carpeting. The resulting contaminations can last for years without extensive remediation. Homes may be filled with residue from acetone, red phosphorus, and other toxic agents. Waste may consist of corrosives and flammables that have been dumped down sinks, toilets, tubs, and in the environment.

Threat to Children, Medical Concerns and Long-term Effects

According to a program coordinator with the National Jewish Medical and Research Center, a leading researcher on the impact of methamphetamine production, long-term health risks could include damage to the lungs, liver, kidneys, and cancer. Individuals with existing medical conditions and young children are at higher risk.[14]

In Oregon, one-third to one-half of the children found in meth labs have tested positive for methamphetamine, via urinalysis testing, due to accidental ingestion or passive inhalation of the drug.[15] Pediatric patients with methamphetamine poisoning may experience tachycardia, agitation, inconsolable crying, irritability, and vomiting.[16] The most common complication of meth poisoning is rhabdomyolyis, which is the breakdown of muscle fibers that are then released in to the blood and may result in kidney damage.[17]

Reasons there is Limited Data on the Long-term Health Effects

There is limited data available on the long-term health effects caused by exposure to the chemicals utilized in methamphetamine manufacturing. Knowledge in this area is limited due to the following reasons:[18]

- Clandestine laboratories have only occurred in the last 10 years and their health effects have been studied for an even shorter period of time.
- Restrictions on tracking health records of minor children.

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[10] An Epidemiology Publication of the Oregon Department of Human Services. Children in Methamphetamine 'Labs' in Oregon. Vol. 52, No. 16. August 12, 2003.
[11] Clandestine drug laboratories are used in the illicit production of illegal drugs.
[12] State of North Carolina. Department of Health and Human Services. Illegal Methamphetamine Laboratory Decontamination and Reoccupancy Guidelines. April 2005. http://www.epi.state.nc.us/epi/oii/methguidelines.pdf
[13] Minnesota Department of Health. Lab Cleanup. http://www.health.state.mn.us/divs/eh/meth/lab/labcleanup.html (February 11, 2006).
[14] Highlights from the People article.
[15] An Epidemiology Publication of the Oregon Department of Human Services. Children in Methamphetamine "Labs" in Oregon. Vol. 52, No. 16. August 12, 2003.
[16] Ibid.
[17] Ibid.
[18] U.S. Congress. House Committee on Science. 2005. "Congressional Testimony by John Martyny." 109th Congress. http://www.house.gov/science/hearings/full05/mar3/Martyny.pdf (February 7, 2006).

- It is difficult to determine the magnitude of the exposure to children in a home not only during, but after a cook has taken place. To date, contamination studies of controlled cooks have only occurred in buildings slated for demolition.[19]

MANUFACTURING OF METHAMPHETAMINE

There are different levels of clandestine laboratories i.e. "superlabs" and "mom and pop" labs. Large-scale production by "superlabs" is predominantly done in Mexico, a major producer or transshipment point for much of the methamphetamine entering America.[20]

The production of methamphetamine is a relatively simple process and can be carried out by individuals without special knowledge or expertise in chemistry. Recipes number in the hundreds and are constantly evolving. There are well over 300 substances that can be used to produce meth. However, there are two primary methods for manufacturing methamphetamine.

Red Phosphorus

The red phosphorous method of manufacturing methamphetamine involves the use of a number of readily obtained materials, including solvents, iodine, hydrogen chloride gas (which can be made by combining sulfuric acid and rock salt), sodium hydroxide, and red phosphorus.[21] Red Phosphorus, for example, can be obtained from match stick heads and flares.

Red Phosphorus labs have the following dangers: phosphine gas production, acid gas generation, acutely corrosive and toxic atmospheres, flammable and explosive atmospheres and oxygen deficient atmospheres. A study[22] on controlled cooks revealed significant exposure to solvents, phosphine,[23] iodine, hydrogen chloride, and methamphetamine aerosol.[24] Due to the spread of methamphetamine during this cooking process, virtually all items within the house as well as all people, pets, toys, etc. become contaminated with methamphetamine.[25] Levels of exposure are exceptionally high for children and infants, who due to their developing physiology and their inquisitive oral habits, are exposed to high levels of hazardous chemicals.[26]

Birch Reduction

This method is also referred as the "Nazi" or "Ammonia" method. This method uses lithium metal from batteries and anhydrous ammonia from fertilizer and refrigeration "chillers" in the reduction of ephedrine/pseudoephedrine.

Birch Reduction labs have the following dangers: electroplating sodium metal from sodium hydroxide; sodium hydroxide which may cause skin or lung irritation; a flammability and irritant toxicity hazard from

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[19] Researchers have requested federal dollars to conduct long-term research at a secure location such as Los Alamos, New Mexico.
[20] U.S. Congress. House Committee on Government Reform, Subcommittee on Criminal Justice. 2005. "Statement by Scott Burns, Deputy Director for State and Local Affairs, Office of National Drug Control Policy." 109th Congress.
[21] U.S. Congress. House Committee on Science. 2005. "Congressional Testimony by John Martyny." 109th Congress. http://www.house.gov/science/hearings/full05/mar3/Martyny.pdf (February 7, 2006).
[22] The study was conducted by John Martyny, Ph.D., C.I.H., with the Department of Preventative Medicine at the University of Colorado and the National Jewish Medical Research Center in Denver, Colorado.
[23] Phosphine is a gas produced when the solution of iodine, water, ephedrine, and red phosphorous is heated. This is a gas that may cause severe pulmonary irritation resulting in pulmonary edema and death. At lower levels may cause nausea, vomiting, headache, and chest tightness, which are symptoms frequently reported by exposed law enforcement personnel at the time of seizure.
[24] U.S. Congress. House Committee on Science Committee Testimony. 2005. "Congressional Testimony by John Martyny." 109th Congress. http://www.house.gov/science/hearings/full05/mar3/Martyny.pdf (February 7, 2006).
[25] Ibid.
[26] Ibid.

concentrated ammonia atmospheres; the violent reaction of water with sodium or lithium metals; a flammable, explosive atmosphere; an acutely corrosive atmosphere because of the acutely reactive metals used. Phosphine and aerosol iodine are not produced in this method. The levels of anhydrous ammonia produced during these cooks are significantly high. The National Institute of Occupational Safety and Health currently recommends that ammonia exposure not exceed 300 parts per million (ppm). However, a meth cook can easily reach 500 ppm of ammonia or more.[27]

Examples of Common Names/Uses for Chemicals in Methamphetamine Laboratories[28]	
Chemical	**Common Name or Product Used**
Acetone	Fingernail polish remover, solvents
Acetic Acid	Vinegar
Alcohol, isopropyl	Rubbing Alcohol
Ammonia (anhydrous)	Fertilizer, used in chillers
Ethyl ether	Computer dust-off
Freon	Refrigerant, propellants
Hydrochloric acid/muriatic acid	Iron ore processing, mining, concrete cleaner
Iodine (crystals)	Antiseptic, catalyst
Lithium metal	Batteries
Methylene chloride	Paint remover, solvent
Phosphoric acid	Fertilizer
Red phosphorus	Match striker plates, road flares
Sulfuric acid	Battery acid, drain cleaner
Toluene	Brake cleaner fluid

LAW ENFORCMENT RESPONSE

How Does a Typical Clandestine Laboratory Seizure Occur?

Typically, law enforcement gets a call or report of a potential clandestine laboratory. Depending on the validity of the information a response team (which may be a combination of local, state or federal officers) is dispatched, or a first responder (city police department or county sheriff) goes to the location, to verify if there is a potential clandestine lab. Once confirmed, the location is evacuated and a clandestine laboratory response team responds to begin the investigation. Once all the appropriate photos, evidence sampling, and other investigative issues are taken care of, a contract vendor (as part of the federal COPS program) responds to the scene to remove all chemicals, glassware, equipment, etc.

All law enforcement personnel who investigate and dismantle labs must be clandestine laboratory certified, which requires attending specialized training that is sanctioned by the Drug Enforcement Administration (DEA) and the Occupational Safety and Health Administration (OSHA). Due to the hazards of entering a clandestine lab all personnel who investigate and dismantle labs are required to wear personal protective equipment. Below is the basic list of the equipment that must be used and the associate costs. The (*) denotes equipment that has to be discarded after each laboratory investigation due to contamination.

No remediation is done to the structure or the property, simply the removal of all chemicals and lab items. If there are containers of chemicals outside the premises that pose a threat to the environment, or any other indicators, the Department of Environmental Protection is called to handle soil and/or water sampling and cleanup. If children are present, the Department of Children and Families is called to the scene. Nothing may be removed from the house and taken with the children or any arrestees due to contamination.

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[27] Ibid.

[28] State of North Carolina. Department of Health and Human Services. Illegal Methamphetamine Laboratory Decontamination and Reoccupancy Guidelines. April 2005. http://www.epi.state.nc.us/epi/oii/methguidelines.pdf

2006 Clandestine Laboratory Investigators Personal Protective Equipment (PPE) List	
Description	**Total Cost**
Self Contained Breathing Apparatus 30-Minute Cylinder	$2,134.00
Clan Lab Monitor Field and Investigators Detector Kit	2,905.00
Ballistic Helmet and Vest	1,055.45
SWAT Coverall, Hood, Gloves, Respirator w/filter, gloves and other equipment*	486.70
TOTAL	$6,581.15

REMEDIATION STANDARDS

National Guidelines for the Cleanup of Clandestine Laboratories and Determining Cleanliness

The Office of National Drug Control Policy is in the process of revising the Guidelines for the Cleanup of Clandestine Drug Laboratories. The so-called "Red Book" includes voluntary standards, lessons learned, and best practices for methamphetamine laboratory cleanup and the removal of hazardous materials found at seized clandestine laboratories for federal, state, and local law enforcement and environmental officials.[29]

A problem with remediation of a clandestine laboratory is determining an acceptable level of "cleanliness" to assure the public that there are not any potential health risks. Currently, there are no national standards for remediated labs, and a baseline definition of "clean" is not available.[30] Fundamental research describing standards for "clean" still need to occur.[31]

There is an ongoing debate about the effectiveness of using a feasibility-based standard rather than a long-term clinical standard. Because research into the long-term health effects associated with clandestine laboratories has just recently begun, health or risk based standards have not yet been determined.[32]

Remediation Standards in Other States

According to the National Alliance for Model State Drug Laws,[33] several states currently regulate the cleanup and remediation of clandestine laboratories, but state statutes specifically relating to the cleanup and remediation of clandestine laboratories vary from state to state.[34]

Given the growing concern regarding cleanup and remediation issues, the variety of approaches among states, the increasing number of states dealing with former meth labs, and the changing nature of labs, the Alliance has convened a national working group to address these issues.[35] The Alliance is drafting a model act or model guidelines for the cleanup and remediation of methamphetamine laboratories that should be released next year.[36]

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[29] U.S. Congress. House Committee on Government Reform, Subcommittee on Criminal Justice. 2005. "Statement by Scott Burns, Deputy Director for State and Local Affairs, Office of National Drug Control Policy." 109th Congress.
[30] U.S. Congress. House Committee on Science. 2005. "Testimony of Robert Bell, Ph.D., President, Tennessee Technological University." 109th Congress.
[31] Ibid.
[32] Ibid.
[33] The National Alliance for Model State Drug Laws is a nonprofit bipartisan organization that resulted from the President's Commission on Model State Drug Laws. It was created to be a resource to assist states in assessing needs, strategizing, and implementing laws and policies to address alcohol and other drug problems.
[34] U.S. Congress. House Committee on Science. 2005. "Statement of Sherry Green, Esq., Executive Director of the National Alliance for Model State Drug Laws." 109th Congress.
[35] Ibid.
[36] Ibid.

The two most commonly used feasibility-based decontamination standards for methamphetamine is 0.1 micrograms per 100 square centimeters and 0.5 micrograms per square foot. A microgram is one millionth of gram and there are 28.3 grams in an ounce. One hundred square centimeters is equivalent to the area about the size of a 3X5 index card. Arizona, North Carolina, Tennessee, and Washington are among several states that require an indoor air quality standard of 0.1 micrograms per 100 square centimeters for methamphetamine. Several other states such as Tennessee, Washington, and California also regulate the level of lead, mercury and volatile organic compounds.

Several states have implemented policy standards to establish guidelines in rule. This allows for changes in indoor air quality standard values as research on levels of health risk improve. Oregon has set a policy standard of 0.5 micrograms per square foot; for methamphetamine; 10 micrograms per square foot for lead; and 0.05 micrograms per square foot for mercury.

Mercury and Lead Standards Recommended by the Environmental Protection Agency

Lead and mercury were formerly important contaminants with older "meth" manufacturing but are less prevalent in current labs.[37] Under the Environmental Protection Agency (EPA) standards, lead is considered a hazard if there are greater than: 40 micrograms of lead in dust per square foot on floors; 250 micrograms of lead in dust per square foot on interior window sills and 400 parts per million (ppm) of lead in bare soil in children's play areas or 1200 ppm average for bare soil in the rest of the yard.[38]

According to the EPA, if mercury levels in a waste exceed the Toxicity Characteristic Leach Test[39] (TCLP) level of 0.2 milligrams per liter for mercury, then the waste is identified as a hazardous waste based on toxicity.[40] Certain mercury-containing wastes are identified as hazardous wastes based on whether they are listed as hazardous in whole or in part because of the presence of mercury.

DECONTAMINATION PROCESS AND DEMOLITION

The cleanup of residual substances that may persist on surfaces and furnishings may involve: removal of surface material layers; use of encapsulants and fixative sealers; neutralization of corrosives; steam cleaning; use of industrial steam and pressure washers; use of detergent washers; use of chemical neutralizers/cover-ups and "bake-out" of a property."[41] In rare cases of severe contamination, effective cleanup may only be accomplished by demolition of the contaminated structure.[42] Based on the known physical properties of the chemicals associated with methamphetamine production, there is no current scientific evidence to suggest a continuing human health risk after a thorough decontamination.[43]

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[37] The University of Arizona Mel and Enid Zuckerman College of Public Health. Hazardous Chemicals in Illicit Methamphetamine and Amphetamine Laboratories. http://www.publichealth.arizona.edu/divisions/environ_com_hlth/popups/hazardous_chemicals.htm (February 11, 2006).

[38] Environmental Protection Agency. Residential Lead Hazard Standards, TSCA Section 403. 2001. http://www.epa.gov/lead/pubs/leadhaz.htm (February 11, 2006).

[39] This is a procedure that is designed to determine the mobility of both organic and inorganic analytes are present in liquid, solid, and multiphasic wastes and is used to determine if a waste meets the definition of toxicity, under federal law.

[40] Environmental Protection Agency. Hazardous Waste Identification Regulations. http://www.epa.gov/epaoswer/hazwaste/mercury/reg_stand.htm#universal

[41] Chesley, Michelle R., M.D., Department of Emergency Medicine, Howard University Hospital. 1999. Methamphetamines: an epidemic of clandestine labs and health risk. http://www.health.state.mn.us/divs/eh/meth/lab/mchesley.pdf (February 11, 2006).

[42] Colorado Department of Public Health and Environment. Cleanup of Clandestine Methamphetamine Labs Guidance Document. 2003. http://www.cdphe.state.co.us./hm/methlab.pdf (February 11, 2006.)

[43] Oregon Department of Human Services, Drug Lab Clean-up Program. "Chemicals used in Methamphetamine Manufacture, http://www.oregon.gov/DHS/ph/druglab/chemicals.shtml (February 11, 2006).

AUTHORITY TO QUARANTINE

Current Statutory Provisions for Quarantines

According to s. 381.0011, F.S., it is the duty of the Department of Health to:

- Administer and enforce laws and rules relating to sanitation, control of communicable diseases, illnesses and hazards to health among humans and from animals to humans, and the general health of the people of the state.
- Cooperate with and accept assistance from federal, state, and local officials for the prevention and suppression of communicable and other diseases, illnesses, injuries, and hazards to human health.
- Declare, enforce, modify, and abolish quarantine of persons, animals, and premises as the circumstances indicate for controlling communicable diseases or providing protection from unsafe conditions that pose a threat to public health, except as provided in ss. 384.28 and 392.545-392.60, F.S.
    - The department is required to adopt rules to specify the conditions and procedures for imposing and releasing a quarantine. The rules must include provisions related to:
        - The closure of premises.
        - The movement of persons or animals exposed to or infected with a communicable disease.
        - The tests or treatment, including vaccination, for communicable disease required prior to employment or admission to the premises or to comply with a quarantine.
        - Testing or destruction of animals with or suspected of having a disease transmissible to humans.
        - Access by the department to quarantined premises.
        - The disinfection of quarantined animals, persons, or premises.
        - Methods of quarantine.
    - Any health regulation that restricts travel or trade within the state may not be adopted or enforced in this state except by authority of the department.
- It is also the duty of the Department of Health to provide for the dissemination of information to the public relative to the prevention, control, and cure of diseases, illnesses, and hazards to human health.

Current Statutory Authority for the Enforcement of a Quarantine by Law Enforcement

Section 381.0012(5), F.S., provides that it is the duty of every state and county attorney, sheriff, police officer, and other appropriate city and county officials upon request to assist the department or any of its agents in enforcing the state health laws and the rules adopted in chapter 38, F.S. The department may also commence and maintain all proper and necessary actions and proceedings to compel the performance of any act specifically required of any person, officer, or board by any law of this state relating to public health.

C. SECTION DIRECTORY:

Section 1. Amends s. 893.02, F.S., to provide definitions for clandestine laboratory, contaminated, decontamination, decontamination specialist, and residential property.
Section 2. Creates s. 893.121, F.S., to provide for a quarantine of any residential property where clandestine laboratory activities occur; the establishment of a uniform notice and letter; provide that a notice is posted at the site of a quarantine; provide that a letter be sent to a residential property owner or property manager; provide an alternative to residential property owners to have a quarantine lifted; and provide limitations and enforcement provisions for habitation of quarantined residential property.

Section 3. Creates s. 893.122, F.S., to provide the option of demolition of contaminated residential property under certain conditions; provide immunity from health-based civil actions for residential property owners who have met certain criteria; and provide an exception from the immunity clause for individuals convicted of operating the clandestine laboratory.
Section 4. Creates s. 893.123, F.S., to provide clandestine laboratory decontamination standards; provide guidelines for issuance of a certificate of fitness to indicate that decontamination is complete; and provide rule-making authority to the department.
Section 5. Creates s. 893.124, F.S., to require the department to compile and maintain a list of persons authorized to perform clandestine laboratory cleanup; provide qualifications for persons authorized to perform cleanup; provide authority for a decontamination specialist to request documents from law enforcement; provide for the placement of liens on contaminated residential property to recoup costs; require clandestine laboratory cleanup specialists to repair, replace, or remediate a contaminated residential property such that it tests below specified values; provide for a form to indicate that appropriate cleanup has occurred; and provide for the issuance of a certificate of fitness.
Section 6 through 12 amends ss. 465.016, 465.023, 856.015, 893.135, 944.47, 951.22, and 985.4046, F.S., to correct cross-references.
Section 13. Provides that the bill will take effect on July 1, 2006

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   No dedicated source of revenue. The bill provides a mechanism to recoup fees by placing a lien on residential property.

2. Expenditures:

   According to the Department of Health, the bill is expected to have an estimated fiscal impact of $2.5 million dollars for the first year of implementation. However, the proposed strike-all amendment significantly decreases the fiscal impact to the Department of Health and alters the role of the department by transferring the assessment of decontamination to qualified independent contractors in the private sector.

   According to the Department of Health, in researching the possible financial implications of the regulation of clandestine drug laboratories, federal reports of clandestine drug laboratory seizures were reviewed. Additionally, a representative of the State of Tennessee clandestine drug laboratory assessor and remediator licensing program was interviewed to estimate the work load requirements in performing an assessment of a building used as a clandestine drug laboratory.

   Currently in Tennessee, clandestine drug laboratory assessors receive $1,500 to $5,000 in professional fees prior to sample analysis fees. Assuming $200 per hour for service time indicates that it is taking from 7 to 25 hours to perform assessments of sites used as clandestine drug laboratories. Additionally, in the average home used as a clandestine laboratory, a minimum of 24 surface swipe samples for methamphetamine are taken at an analysis cost of $80 per swipe, or $1,920 per average home.

   During the 2004 year, 276 clandestine drug laboratories were reported for Florida to the National Clandestine Laboratory Database. The number has increased 1200% since 1999, or an average of over 50% per year. The highest number of clandestine drug laboratories reported for any state was in Missouri where they found 2,788 clandestine drug laboratories in 2004. Reporting the number of clandestine drug laboratory incidents is not a requirement and is under reported. Considering that Missouri has a populace less than a 1/3rd Florida's indicates that as the methamphetamine production moves east, the number of clandestine drug laboratories found in Florida could easily exceed 500 per year. According to the Department of Health, if the current average rate of

clandestine drug laboratory growth continues unabated, over 600 clandestine drug laboratories could be found annually in Florida by 2007 and over 2000 by 2010. [*See D. Fiscal Comments.* For an explanation of growth projections.]

According to DOH, using an estimate of 500 drug labs per year and a median time of 16 hours per building assessment places an 8,000 hour personnel requirement on DOH, or an additional 4.32 FTEs statewide if one individual was to investigate each site. Since the primary duty of the decontamination specialist is to evaluate an unknown chemical hazard, two man response teams with appropriate personnel protection gear would be required to meet safety standards for a total of approximately 10 FTEs.

It is assumed the individuals would be hired as Environmental Specialist II's. Because the individuals would be assessing a chemical hazard, they would require appropriate training with annual refreshers. Level B protective gear would be required for entering the buildings to perform the assessments. This requires additional annual fitness for duty evaluations to be permitted to work in level B protective gear. A support vehicle with appropriate decontamination facilities for their equipment would be necessary for the decontamination specialists.

Should the evaluation of buildings used as clandestine drug laboratories include analysis of lead, mercury, volatile organic compounds and methamphetamine residue, the purchase, maintenance and replacement of specialized field equipment will have to be included in annual budgets. For lead, an XRF analyzer costs $20,000 each with annual recalibration and maintenance of $2,500. For mercury analysis, Lumex vapor analyzers cost $12,900 each with an annual recalibration and maintenance costs of $500 per year. VOC photo ionization detectors (PID) cost $2,300 but have a useful life of approximately 18 to 24 months at which time they require replacement as well as an annual calibration requirement. DOH estimates that methamphetamine residue analysis costs annually could be $1,920 per location and 500 locations or $960,000 per year.

The adoption and development of multiple rules, the development of standardized forms, coordination and support of field staff activities, authorization of cleanup personnel, qualification of decontamination specialists, compilation and publication of authorized and qualified specialists and persons, creation and maintenance of websites would require 4 additional FTE's at DOH headquarters. These FTE's would include one Administrative Secretary, two Environmental Specialist III's and one Environmental Administrator.

During the implementation and rule making period it will be necessary for DOH to hold meetings with experts to determine reasonable, appropriate and protective standards for the testing and cleanup of clandestine laboratories. DOH anticipates the need for convening a panel of toxicologists, industrial hygienists, hazardous material and waste specialists, medical professionals, decontamination and cleanup specialists, local/state law enforcement, public health and environmental agency representatives. The purpose of this panel would be to advise DOH regarding reasonable, appropriate and protective measures specific to the requirements of this bill. The panel experts would be volunteers with the DOH paying for travel costs to meetings. We anticipate a panel of no more than 14 experts assembling for six meetings of three days, two nights in duration.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Costs for clandestine laboratory cleanup will vary depending upon the nature and extent of the cleanup needed. According to the Washington State Department of Health, decontamination costs average $6,500 per 1,200 square-feet.[44] According to an Arkansas news article, clean-up costs generally range from $2,000 to $10,000; depending on the size of the lab.[45]

D. FISCAL COMMENTS:

Fiscal impacts may be much less than the estimates provided by the Department of Health. According to statistics complied by the Florida Department of Law Enforcement, the State seized 319 clandestine laboratories in 2004 and 338 in 2005. Based on this data it appears that the growth in the number of clandestine labs is slowing. The 2005 legislation that placed quantity and point of sale restrictions on over-the-counter cold medicines that contain ephedrine, pseudoephedrine or phenylpropanolamine is anticipated to significantly limit or reduce the number of labs. States that have placed restrictions on the sale of ephedrine, pseudoephedrine or phenylpropanolamine have seen a dramatic decrease in the incidence of clandestine laboratories.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

There are several constitutional issues that have been mentioned as potential items of concern, i.e., applying a lien on homestead property, the immunity from health-based civil action, and the quarantine of personal property. As currently provided in the bill, applying a lien to contaminated property has the potential to limit the fiscal impact on the Department of Health. It would permit the department to recoup expenses and it encourages property owners to become more active in the management of their rental property. The immunity from health-based civil action provision encourages property owners to decontaminate their property. Authority to quarantine a property that may pose a health hazard is well established for instances where a quarantine is meant to protect the public from harm. Each issue is discussed below.

Homestead Property and Liens

This bill creates s. 893.124(5), F.S., which grants the Department of Health the authority to file a lien on the residential property with the clerk of the circuit court to encourage property owners to follow the provisions for decontaminating or demolishing residential property that is found to be contaminated by a clandestine laboratory. This bill also provides that the lien will have the same force, effect, and priority of a judgment lien.

One constitutional limitation on the lien provision in the bill depends on whether the property that is subject to the lien is the property owner's homestead. Article X, s.4, Fla. Const. provides the following:

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[44] Washington State Department of Health, Division of Environmental Health, Office of Environmental Health and Safety. Information for Landlords and Property Owners. http://www.doh.wa.gov/ehp/ts/CDL/landlordtips.htm (February 11, 2006).
[45] Bradford, Michelle. 2000. U.S. Denies funds for State Meth Cleanup; Officials Mull Options. http://www.kci.org/meth_info/sites/ark_drug%20cleanup.htm (February 12, 2006).

SECTION 4. Homestead; exemptions.--

(a) There shall be exempt from forced sale under process of any court, and no judgment, decree or execution shall be a lien thereon, except for the payment of taxes and assessments thereon, obligations contracted for the purchase, improvement or repair thereof, or obligations contracted for house, field or other labor performed on the realty, the following property owned by a natural person:
(1) a homestead, if located outside a municipality, to the extent of one hundred sixty acres of contiguous land and improvements thereon, which shall not be reduced without the owner's consent by reason of subsequent inclusion in a municipality; or if located within a municipality, to the extent of one-half acre of contiguous land, upon which the exemption shall be limited to the residence of the owner or the owner's family;
(2) personal property to the value of one thousand dollars.
(b) These exemptions shall inure to the surviving spouse or heirs of the owner.
(c) The homestead shall not be subject to devise if the owner is survived by spouse or minor child, except the homestead may be devised to the owner's spouse if there be no minor child. The owner of homestead real estate, joined by the spouse if married, may alienate the homestead by mortgage, sale or gift and, if married, may by deed transfer the title to an estate by the entirety with the spouse. If the owner or spouse is incompetent, the method of alienation or encumbrance shall be as provided by law.

The Supreme Court of Florida has ruled that the exemptions to homestead found in the Florida Constitution must be liberally construed and the exemptions protect the homestead against every type of claim and judgment except those specifically mentioned in the constitutional provision itself.[46] Therefore, if the property has been designated homestead property before being subject to the lien pursuant to this bill, then the creditor will not be able to place a lien on the property whether or not the residential property is found to be contaminated due to the existence of a clandestine laboratory. However, if the residential property is sold and the proceeds are not reinvested in another homestead property within a reasonable time, then the creditor will be able to reach the proceeds from the sale of the property. Surplus proceeds from any sale of homestead property will not be protected and are subject to creditor claims. Furthermore, property that is abandoned can lose its homestead designation, and at that point, a creditor could attach a lien on the property and satisfy the lien through the forced sale of the property. However, abandonment is a question of fact.

Access to Courts

This bill provides that a residential property owner who has met the decontamination standards, or has demolished the residential property "shall have immunity from health-based civil actions brought by any future owner, renter, or other person who occupies the residential property, or a neighbor of such residential property, in which the alleged cause of the injury or loss is the existence of the clandestine laboratory". This provision in the bill could possibly be an unconstitutional violation of Article I, s. 21, Fla. Stat.

Article I, s. 21, Fla. Stat. provides the following:

SECTION 21. Access to courts.--The courts shall be open to every person for redress of any injury, and justice shall be administered without sale, denial or delay.

The right to go to court to resolve disputes is a fundamental right.[47] In order to make a claim of denial of access to courts, an aggrieved party must demonstrate that the Legislature has abolished a

[46] *Butterworth v. Caggiano*, 605 So.2d 56 (Fla. 1992)
[47] *DR Lakes Inc. v. Brandsmart U.S.A. of West Palm Beach*, 819 So. 2d 971 (Fla. Dist. Ct. App. 4th Dist. 2002).

common-law right previously enjoyed by the people of Florida.[48] A person's guaranteed access to the courts should not be unduly or unreasonably burdened or restricted.[49] If the Legislature asserts a valid public purpose, it can restrict access to the courts as long as it provides a reasonable alternative to litigation. It may be possible that this bill could be found to be an unreasonable burden to an individual's right of access to courts. This bill is taking away a previously available cause of action to any person who is injured by the negligent use of a person's property simply because the property owner has followed the decontamination or demolition procedures of the bill. The Florida Supreme Court, in the case Kluger v. White, 281 So.2d 1 (Fla. 1973), held that, "where a right of access to the courts for redress for a particular injury has been provided by statutory law predating the adoption of the Declaration of Rights of the Constitution of Florida, or where such right has become a part of the common law of the State, the Legislature is without power to abolish such a right without providing a reasonable alternative to protect the rights of the people of the State to redress for injuries, unless the Legislature can show an overpowering public necessity for the abolishment of such right, and no alternative method of meeting such public necessity can be shown".[50]

Taking of Property

Article X, s. 6, Fla. Stat. provides the following:

> SECTION 6. Eminent domain.--
>
> (a) No private property shall be taken except for a public purpose and with full compensation therefore paid to each owner or secured by deposit in the registry of the court and available to the owner.
> (b) Provision may be made by law for the taking of easements, by like proceedings, for the drainage of the land of one person over or through the land of another.

Takings issues could arise based on the fact that this bill allows a government entity to come in and force a person from their property and restrict any devise of the property until the residential property is decontaminated or demolished. A state law quarantining property pursuant to this bill probably would not be considered a taking. However, although the state may validly exercise its police power in conformance with applicable statutes and rules when it destroys property, its exercise of the police powers can still result in a taking.[51] Full and just compensation is required when the state, pursuant to its police power, destroys healthy but suspect citrus trees to prevent the spread of citrus canker.[52] There is no settled formula for determining when the valid exercise of police power stops and an impermissible encroachment on private property rights begins, but some of the factors which have been considered are:[53]

- Whether there is a physical invasion of the property;
- The degree to which there is a diminution in value of the property or whether the regulation precludes all economically reasonable use of the property;
- Whether the regulation confers a public benefit or prevents a public harm;
- Whether the regulation promotes the health, safety, welfare, or morals of the public;
- Whether the regulation is arbitrarily and capriciously applied; and
- The extent to which the regulation curtails investment-backed expectations.

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[48] *Yachting Promotions, Inc. v. Broward Yachts, Inc.*, 792 So. 2d 660 (Fla. Dist. Ct. App. 4th Dist. 2001); *Strohm v. Hertz Corporation/Hertz Claim Management*, 685 So. 2d 37 (Fla. Dist. Ct. App. 1st Dist. 1996).
[49] *Preferred Medical Plan, Inc. v. Ramos*, 742 So. 2d 322 (Fla. Dist. Ct. App. 3d Dist. 1999); *Swain v. Curry*, 595 So. 2d 168 (Fla. Dist. Ct. App. 1st Dist. 1992).
[50] *Id.* at 4.
[51] *Albrecht v. State*, 444 So. 2d 8 (Fla. 1984); *Conner v. Reed Bros., Inc.*, 567 So. 2d 515 (Fla. Dist. Ct. App. 2d Dist. 1990).
[52] *Department of Agriculture and Consumer Services v. Mid-Florida Growers, Inc.*, 521 So. 2d 101 (Fla. 1988).
[53] *Graham v. Estuary Properties, Inc.*, 399 So. 2d 1374 (Fla. 1981).

Where a regulation creates a public benefit, it is more likely an exercise of eminent domain, and where a public harm is prevented it is more likely an exercise of the police power.[54] Reasonable regulations pursuant to the police power of the state, intended to promote public health, safety, or general public welfare, may be adopted and enforced without violating the constitutional rights of property owners.

B. RULE-MAKING AUTHORITY:

The bill provides the Department of Health rule-making authority to promulgate rules to:

- Establish a 'certificate of fitness' that acts as documentation signifying that a home has been properly decontaminated;
- Establishing the standards for cleanup and testing of clandestine labs;
- Create a uniform notice and letter; and
- Specify the requirements of persons authorized to perform clandestine laboratory cleanup.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Department of Health has voiced concerns regarding their involvement in decontamination of residential properties and the procedural requirements that are set forth in the PCB.

A strike-all amendment will be proposed to stream-line several requirements and processes required in the PCB to addresses the concerns voiced by the department. The proposed strike-all will significantly reduce the fiscal impact to the Department of Health and alter the role of the department by transferring the assessment of decontamination to qualified independent contractors in the private sector.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

[54] *Graham v. Estuary Properties, Inc.*, 399 So. 2d 1374 (Fla. 1981); *State Plant Bd. v. Smith*, 110 So. 2d 401 (Fla. 1959).

A bill to be entitled

An act relating to clandestine laboratory contamination; amending s. 893.02, F.S.; providing definitions; creating s. 893.121, F.S.; providing for quarantine of any residential property where illegal clandestine laboratory activities occurred; providing for establishment of a uniform notice and a uniform letter; providing for posting of specified notice at the site of a quarantine; requiring the sending of a specified letter to a residential property owner or property manager; providing for petitions by certain persons in circuit court to lift such quarantines under certain conditions; prohibiting specified violations relating to such quarantines; creating s. 893.122, F.S.; permitting demolition of quarantined residential property under certain conditions; providing immunity from health-based civil actions for residential property owners who have met specified clandestine laboratory decontamination standards as evidenced by specified documentation; providing an exception to such immunity for persons convicted of manufacturing controlled substances at the site; creating s. 893.123, F.S.; providing clandestine laboratory decontamination standards; providing for certificates of fitness to indicate that decontamination has been completed; providing for rulemaking; creating s. 893.124, F.S.; requiring the Department of Health to compile and maintain lists of decontamination specialists and persons authorized to perform clandestine laboratory cleanup; providing for establishment of requirements for persons

authorized to perform clandestine laboratory cleanup; permitting decontamination specialists to request specified documents; providing for specified reports by decontamination specialists; providing for the placement of liens on contaminated residential property for certain costs and removal of such liens; requiring clandestine laboratory cleanup specialists to repair, replace, or remediate damaged materials on a residential property such that the residential property successfully tests less than or equal to specified values; providing for a form to indicate that appropriate cleanup of a clandestine laboratory has occurred; providing for issuance of a certificate of fitness; amending ss. 465.016, 465.023, 856.015, 893.135, 944.47, 951.22, and 985.4046, F.S.; conforming cross-references; providing an effective date.

WHEREAS, methamphetamine use and production is increasing throughout the state, and

WHEREAS, in places where methamphetamine production has occurred, significant levels of chemical contamination may be found, especially in residential properties when the contamination is not decontaminated, and

WHEREAS, children are susceptible to environmental toxicants via the skin, and the ingestion of residual methamphetamine is considered to be a result of hand-to-mouth activities, and

WHEREAS, studies on methamphetamine use during pregnancy showed an increased incidence of intrauterine growth retardation, prematurity, and perinatal complications, and

WHEREAS, once clandestine laboratories have been seized, the public may continue to be harmed by the illegal dumping of chemical byproducts and the chemical residues that remain on the residential property, and

WHEREAS, there are no statewide standards for determining when a site of a seized clandestine laboratory has been successfully decontaminated, and

WHEREAS, the Legislature finds that this act is necessary for the immediate preservation of the public health, safety, and welfare and fulfills an important state interest, NOW, THEREFORE,

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (4), subsections (5)-(20), and subsection (21) of section 893.02, Florida Statutes, are renumbered as subsection (6), subsections (9)-(24), and subsection (26), respectively, and new subsections (4), (5), (7), (8), and (25) are added to that section, to read:

893.02 Definitions.--The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(4) "Clandestine laboratory" means any location and proximate areas set aside or used that are likely to be contaminated as a result of manufacturing, processing, cooking, disposing, or storing, either temporarily or permanently, any substances in violation of this chapter, except as such activities are authorized in chapter 499.

(5) "Contaminated" or "contamination" means containing levels of chemicals at or above the levels established under s. 893.123(1) as a result of clandestine laboratory activity.

(7) "Decontamination" means the process of reducing the level of a known contaminant to an amount acceptable for human reoccupancy using currently available methods and processes.

(8) "Decontamination specialist" means a certified industrial hygienist, local health officer, environmental specialist, or other employee of the department or qualified contractor that the department deems qualified to determine if a clandestine laboratory is contaminated.

(25) "Residential property" means a dwelling unit used, or intended for use, by an individual or individuals as a permanent residence. The term includes improved real property of between one and four dwellings; a condominium unit, as defined in s. 718.103(27); a cooperative unit, as defined in s. 719.103(24); or a mobile home or manufactured home, as defined in s. 320.01(2). The term does not include a hotel, motel, campground, marina, or timeshare unit.

Section 2. Section 893.121, Florida Statutes, is created to read:

893.121 Quarantine of residential property.--

(1) The purpose of the quarantine provided for in this section is to prevent exposure of any person to the hazards associated with clandestine laboratory activities and provide protection from unsafe conditions that pose a threat to the public health, safety, and welfare. The department has the authority to quarantine residential property under s. 381.0011.

(2) Whenever a law enforcement agency secures evidence from any residential property where illegal clandestine laboratory activities occurred, the law enforcement agency securing evidence shall, as part of its duty to assist the department under s. 381.0012(5), enforce a quarantine on the residential property until it is deemed decontaminated for human reoccupancy. Enforcement does not require the posting of 24-hour law enforcement personnel. The residential property shall remain quarantined until a decontamination specialist determines the residential property is not contaminated or the law enforcement agency receives documentation that the residential property may be reoccupied.

(3) The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 to establish a uniform notice to post at the site of a quarantined clandestine laboratory and a uniform letter that will be sent to the residential property owner or the manager of the residential property under quarantine by the law enforcement agency enforcing the quarantine. The material in the letter and notice shall include, but not be limited to:

(a) That the residential property has been quarantined and a clandestine laboratory was seized on or inside the residential property.

(b) The date of the seizure.

(c) The name and contact telephone number of the agency posting the quarantine.

(d) A statement specifying that hazardous substances, toxic chemicals, or other hazardous waste products may have been present and may remain on or inside the residential property and

that exposure to the substances may be harmful and may pose a threat to public health and the environment.

(e) A statement that it is unlawful for an unauthorized person to enter the contaminated residential property and that the removal of any notice of the quarantine is a second degree misdemeanor under s. 381.0025(1).

(f) A statement explaining how to have the quarantine lifted.

(4) The law enforcement agency that quarantines the residential property shall be responsible for posting the uniform notice, as provided in subsection (3), and, to the extent possible, notify the residential property owner or the manager of the residential property with a uniform letter, as provided in subsection (3), within 5 working days from the date of quarantine.

(5) Upon quarantine, the law enforcement agency shall immediately notify the local health officer that a residential property in the officer's area was quarantined. Within 3 working days after receiving the notification, the health officer shall dispatch a decontamination specialist to determine whether the residential property is contaminated.

(6) Any person who has an interest in a residential property that is quarantined pursuant to this section may file a petition in the circuit court in which the residential property is located to request that the quarantine of the residential property be lifted for one of the following reasons:

(a) The residential property was wrongfully quarantined; or

(b) The residential property has been properly decontaminated as specified in s. 893.122(1) or s. 893.123 and

may be reoccupied, but the law enforcement agency or the department that imposed the quarantine refuses or fails to lift the quarantine.

(7) No person shall inhabit the quarantined residential property, offer the residential property to the public for temporary or indefinite habitation, or remove any notice of the quarantine. Any person who willfully violates a provision of this subsection commits a second degree misdemeanor under s. 381.0025(1).

Section 3. Section 893.122, Florida Statutes, is created to read:

893.122 Option of demolition; immunity from liability from health-based civil actions.--

(1) Upon notification from a law enforcement agency that clandestine laboratory activities have occurred on a residential property or when such activity is discovered and the residential property owner has received notice of a quarantine and documentation that the residential property is contaminated, the owner of such property shall meet the clandestine laboratory decontamination standards in compliance with s. 893.123 unless the residential property owner, at the owner's discretion, elects to demolish the contaminated residential property. The demolition and removal of materials must meet the requirements of the Occupational Safety and Health Administration; United States Environmental Protection Agency regulations pertaining to the generation, storage, transport, and disposal of hazardous wastes; and any state or local requirements.

(2) A residential property owner who has met the clandestine laboratory decontamination standards, as evidenced by

documentation completed by persons authorized to perform cleanup of properties where clandestine laboratory activities have occurred and as evidenced by a copy of the results that were provided to the law enforcement agency and the department to remove the quarantine, or has demolished the residential property in compliance with subsection (1), shall have immunity from health-based civil actions brought by any future owner, renter, or other person who occupies such residential property, or a neighbor of such residential property, in which the alleged cause of the injury or loss is the existence of the clandestine laboratory. However, a person with a conviction, as defined in s. 944.607, for the manufacture of any substance regulated under this chapter on the residential property where clandestine laboratory activities occurred shall not have the immunity provided in this subsection.

Section 4. Section 893.123, Florida Statutes, is created to read:

893.123 Clandestine laboratory decontamination standards.--

(1) The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 establishing standards for the cleanup and testing of clandestine laboratories. Residential property contaminated by clandestine laboratory activity may be reoccupied only if all of the following standards are met with regard to that property:

(a) The total level of lead is less than or equal to 20 micrograms per cubic meter.

(b) The level of methamphetamine on any indoor surface is less than or equal to 0.1 micrograms per 100 square centimeters.

(c) The level of mercury is less than or equal to 50 nanograms per cubic meter for indoor air.

(d) The level of volatile organic compounds, as defined in 40 C.F.R. s. 51.100, is less than or equal to 1 part per million for indoor air.

(2) The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 to establish a certificate of fitness that shall act as appropriate documentation to submit to the law enforcement agency that the residential property has been properly decontaminated. The certificate of fitness shall:

(a) Be issued by a decontamination specialist who determines the quarantined residential property may be reoccupied based on the standards specified in subsection (1); or

(b) Be issued to the residential property owner at the completion of decontamination by a person authorized to perform cleanup of clandestine laboratories that have been quarantined.

Section 5. Section 893.124, Florida Statutes, is created to read:

893.124 Decontamination and clandestine laboratory cleanup specialists.--

(1)(a) The department shall compile and maintain a list of decontamination specialists and a list of persons authorized to perform clandestine laboratory cleanup of properties where clandestine laboratory activities have occurred. These lists shall be posted on the department's Internet website.

(b) Persons authorized to perform clandestine laboratory cleanup of properties should have knowledge and skill in handling toxic substances, such as certified industrial hygienists. The department shall adopt rules pursuant to ss. 120.536(1) and

120.54 specifying the requirements for persons authorized to perform clandestine laboratory cleanup. For purposes of this section, these persons shall be designated "clandestine laboratory cleanup specialists."

(2) In determining whether a clandestine laboratory is contaminated, the decontamination specialist may request copies of any law enforcement reports, forensic chemist reports, and any hazardous waste manifests to evaluate the following:

(a) The length of time the residential property was used as a clandestine laboratory.

(b) The extent to which the residential property was exposed to chemicals used in clandestine laboratory activities.

(c) The chemical process that was involved in the clandestine laboratory activities.

(d) The chemicals that were removed from the residential property.

(e) The location of the clandestine laboratory activities in relation to the habitable areas of the residential property.

(3) If the decontamination specialist determines that the residential property is not contaminated, the decontamination specialist shall send a copy of the documentation to the residential property owner and the local law enforcement agency, remove all quarantine notices posted pursuant to s. 893.121, and prepare a written document that includes the following:

(a) Findings and conclusions.

(b) The name of the residential property owner and mailing and street address of the residential property or the parcel identification of the residential property, if applicable.

(4) If the decontamination specialist determines that the residential property is contaminated, the decontamination specialist shall:

(a) Prepare written document containing the findings, conclusions, and test results and a statement specifying that the residential property is contaminated and will remain quarantined until the residential property is decontaminated pursuant to s. 893.122(1) or s. 893.123.

(b) Send a copy of the written document to the residential property owner within 3 working days along with a list of clandestine laboratory cleanup specialists who have been authorized to perform cleanup by the department and information on how to have the quarantine lifted.

(c) Send a copy of the written document to the law enforcement agency within 3 working days from the time of completion of the report.

(5)(a) The department shall file a lien with the clerk of the circuit court on the residential property that is deemed contaminated. The lien shall specify all of the following:

1. The name of the agency on whose behalf the lien is imposed.

2. The date on which the residential property was determined to be contaminated.

3. The legal description and the assessor's parcel number.

4. The record owner of the residential property.

5. The amount of the lien, which shall be the greater of $200 or the costs incurred by the department to determine if the residential property is contaminated, including, but not limited

to, the cost of inspection by the decontamination specialist, the cost of preparing the lien, and the recording fee.

(b) The lien recorded pursuant to this subsection shall have the force, effect, and priority of a judgment lien. The law enforcement agency shall not release the lien until either of the following occurs:

1. The residential property owner satisfies the lien and submits proof, such as a certificate of fitness, that the residential property has been decontaminated pursuant to s. 893.122(1) or s. 893.123 and the law enforcement agency lifts the quarantine; or

2. The lien is otherwise released under applicable law.

(6) The clandestine laboratory cleanup specialist shall repair, replace, or remediate damaged materials on a residential property such that, upon the conclusion of the cleanup, the residential property successfully tests less than or equal to the values specified in s. 893.123(1). The department shall adopt by rule pursuant to ss. 120.536(1) and 120.54 an appropriate form that a clandestine laboratory cleanup specialist shall complete and submit to the department as proof that the appropriate cleanup of a clandestine laboratory has occurred. The information in the form shall include, but is not limited to, the:

(a) Name of the residential property owner and legal description of the property.

(b) Date the cleanup was completed.

(c) Test results, findings, and conclusions.

(d) Method of repair, replacement, or remediation of the residential property.

(e) Name, address, and contact information of the company or individual who performed the cleanup.

(f) Documentation that all hazardous substances, toxic chemicals, or other hazardous waste products that may have been present were removed from the residential property and disposed of properly.

(7) Upon receipt of the completed form and all supporting documentation submitted by the clandestine laboratory cleanup specialist, the department shall issue a certificate of fitness to the clandestine laboratory cleanup specialist. The clandestine laboratory cleanup specialist shall submit the certificate of fitness to the residential property owner and the law enforcement agency as documentation that the property may be reoccupied.

Section 6. Paragraph (s) of subsection (1) of section 465.016, Florida Statutes, is amended to read:

465.016 Disciplinary actions.--

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(s) Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02~~(20)~~ when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship.

Section 7. Paragraph (e) of subsection (1) of section 465.023, Florida Statutes, is amended to read:

465.023 Pharmacy permittee; disciplinary action.--

(1) The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on

probation, or otherwise discipline any pharmacy permittee who has:

(e) Dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02~~(20)~~ when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

Section 8. Paragraph (c) of subsection (1) of section 856.015, Florida Statutes, is amended to read:

856.015 Open house parties.--

(1) Definitions.--As used in this section:

(c) "Drug" means a controlled substance, as that term is defined in ss. 893.02~~(4)~~ and 893.03.

Section 9. Subsection (6) of section 893.135, Florida Statutes, is amended to read:

893.135 Trafficking; mandatory sentences; suspension or reduction of sentences; conspiracy to engage in trafficking.--

(6) A mixture, as defined in s. 893.02~~(14)~~, containing any controlled substance described in this section includes, but is not limited to, a solution or a dosage unit, including but not limited to, a pill or tablet, containing a controlled substance. For the purpose of clarifying legislative intent regarding the weighing of a mixture containing a controlled substance described in this section, the weight of the controlled substance is the

total weight of the mixture, including the controlled substance and any other substance in the mixture. If there is more than one mixture containing the same controlled substance, the weight of the controlled substance is calculated by aggregating the total weight of each mixture.

Section 10. Paragraph (a) of subsection (1) of section 944.47, Florida Statutes, is amended to read:

944.47 Introduction, removal, or possession of certain articles unlawful; penalty.--

(1)(a) Except through regular channels as authorized by the officer in charge of the correctional institution, it is unlawful to introduce into or upon the grounds of any state correctional institution, or to take or attempt to take or send or attempt to send therefrom, any of the following articles which are hereby declared to be contraband for the purposes of this section, to wit:

1. Any written or recorded communication or any currency or coin given or transmitted, or intended to be given or transmitted, to any inmate of any state correctional institution.

2. Any article of food or clothing given or transmitted, or intended to be given or transmitted, to any inmate of any state correctional institution.

3. Any intoxicating beverage or beverage which causes or may cause an intoxicating effect.

4. Any controlled substance as defined in s. 893.02~~(4)~~ or any prescription or nonprescription drug having a hypnotic, stimulating, or depressing effect.

5. Any firearm or weapon of any kind or any explosive substance.

Section 11. Subsection (1) of section 951.22, Florida Statutes, is amended to read:

951.22 County detention facilities; contraband articles.--

(1) It is unlawful, except through regular channels as duly authorized by the sheriff or officer in charge, to introduce into or possess upon the grounds of any county detention facility as defined in s. 951.23 or to give to or receive from any inmate of any such facility wherever said inmate is located at the time or to take or to attempt to take or send therefrom any of the following articles which are hereby declared to be contraband for the purposes of this act, to wit: Any written or recorded communication; any currency or coin; any article of food or clothing; any tobacco products as defined in s. 210.25(11); any cigarette as defined in s. 210.01(1); any cigar; any intoxicating beverage or beverage which causes or may cause an intoxicating effect; any narcotic, hypnotic, or excitative drug or drug of any kind or nature, including nasal inhalators, sleeping pills, barbiturates, and controlled substances as defined in s. 893.02~~(4)~~; any firearm or any instrumentality customarily used or which is intended to be used as a dangerous weapon; and any instrumentality of any nature that may be or is intended to be used as an aid in effecting or attempting to effect an escape from a county facility.

Section 12. Paragraph (a) of subsection (1) of section 985.4046, Florida Statutes, is amended to read:

985.4046 Introduction, removal, or possession of certain articles unlawful; penalty.--

(1)(a) Except as authorized through program policy or operating procedure or as authorized by the facility

superintendent, program director, or manager, a person may not introduce into or upon the grounds of a juvenile detention facility or commitment program, or take or send, or attempt to take or send, from a juvenile detention facility or commitment program, any of the following articles, which are declared to be contraband under this section:

1. Any unauthorized article of food or clothing.

2. Any intoxicating beverage or any beverage that causes or may cause an intoxicating effect.

3. Any controlled substance, as defined in s. 893.02~~(4)~~, or any prescription or nonprescription drug that has a hypnotic, stimulating, or depressing effect.

4. Any firearm or weapon of any kind or any explosive substance.

Section 13. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **PCB HCR 06-03**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Garcia offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 893.02, Florida Statutes, is amended to read:

893.02 Definitions.--The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(1) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a person or animal.

(2) "Analog" or "chemical analog" means a structural derivative of a parent compound that is a controlled substance.

(3) "Cannabis" means all parts of any plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin.

(4) "Clandestine laboratory" means any location and proximate areas set aside or used that are likely to be contaminated as a result of manufacturing, processing, cooking, disposing, or storing, either temporarily or permanently, any substances in violation of this chapter, except as such activities are authorized in chapter 499.

(5) "Contaminated" or "contamination" means containing levels of chemicals at or above the levels defined by the department pursuant to s. 893.123(1) as a result of clandestine laboratory activity.

(6) "Contamination assessment specialist" or "contamination assessor" means a person responsible for assessing the extent of contamination and decontamination by determining the indoor air quality in a residential property based on the standards defined by the department. Upon the conclusion of decontamination, a residential property must successfully test less than or equal to the values defined by the department. The person must have specialized training that provides him or her with the knowledge, skills, and abilities to use quantitative measurement techniques in collecting and assessing specified contamination levels that have the ability to impair human health and well-being.

(7)~~(4)~~ "Controlled substance" means any substance named or described in Schedules I-V of s. 893.03. Laws controlling the manufacture, distribution, preparation, dispensing, or administration of such substances are drug abuse laws.

(8) "Decontamination" means the process of reducing the levels of contaminants to the levels defined by the department pursuant to s. 893.123(1) that allow human reoccupancy using currently available methods and processes.

(9) "Decontamination specialist" means a person responsible for the cleanup, treatment, repair, removal, and decontamination of contaminated materials located in a residential property where clandestine laboratory activities occurred. The person must have the knowledge, skills, and ability to prescribe methods to eliminate, control, or reduce contamination; and must have been trained in the removal, storage, transport, and disposal of hazardous chemicals or chemical residues commonly associated with clandestine laboratory activities.

(10) ~~(5)~~ "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship.

(11) ~~(9)~~ "Department" means the Department of Health.

(12) ~~(6)~~ "Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer thereof or to one who represents that it is his or her intention not to consume or use the same but to transfer the same to the ultimate consumer or user for consumption by the ultimate consumer or user.

(13) ~~(7)~~ "Distribute" means to deliver, other than by administering or dispensing, a controlled substance.

(14) ~~(8)~~ "Distributor" means a person who distributes.

(15) ~~(10)~~ "Hospital" means an institution for the care and treatment of the sick and injured, licensed pursuant to the provisions of chapter 395 or owned or operated by the state or Federal Government.

(16) ~~(11)~~ "Laboratory" means a laboratory approved by the Drug Enforcement Administration as proper to be entrusted with the custody of controlled substances for scientific, medical, or

instructional purposes or to aid law enforcement officers and prosecuting attorneys in the enforcement of this chapter.

(17) ~~(12)~~ "Listed chemical" means any precursor chemical or essential chemical named or described in s. 893.033.

(18) ~~(13)~~ (a) "Manufacture" means the production, preparation, propagation, compounding, cultivating, growing, conversion, or processing of a controlled substance, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation, compounding, packaging, or labeling of a controlled substance by:

1. A practitioner or pharmacist as an incident to his or her administering or delivering of a controlled substance in the course of his or her professional practice.

2. A practitioner, or by his or her authorized agent under the practitioner's supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis, and not for sale.

(b) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug as defined by the Florida Drug and Cosmetic Act. However, this definition does not apply to manufacturers of patent or proprietary preparations as defined in the Florida Pharmacy Act. Pharmacies, and pharmacists employed thereby, are specifically excluded from this definition.

(19) ~~(14)~~ "Mixture" means any physical combination of two or more substances.

(20) ~~(15)~~ "Patient" means an individual to whom a controlled substance is lawfully dispensed or administered pursuant to the provisions of this chapter.

(21) ~~(16)~~ "Pharmacist" means a person who is licensed pursuant to chapter 465 to practice the profession of pharmacy in this state.

(22) ~~(17)~~ "Possession" includes temporary possession for the purpose of verification or testing, irrespective of dominion or control.

(23) ~~(18)~~ "Potential for abuse" means that a substance has properties of a central nervous system stimulant or depressant or an hallucinogen that create a substantial likelihood of its being:

(a) Used in amounts that create a hazard to the user's health or the safety of the community;

(b) Diverted from legal channels and distributed through illegal channels; or

(c) Taken on the user's own initiative rather than on the basis of professional medical advice.

Proof of potential for abuse can be based upon a showing that these activities are already taking place, or upon a showing that the nature and properties of the substance make it reasonable to assume that there is a substantial likelihood that such activities will take place, in other than isolated or occasional instances.

(24) ~~(19)~~ "Practitioner" means a physician licensed pursuant to chapter 458, a dentist licensed pursuant to chapter 466, a veterinarian licensed pursuant to chapter 474, an osteopathic physician licensed pursuant to chapter 459, a naturopath licensed pursuant to chapter 462, or a podiatric

physician licensed pursuant to chapter 461, provided such practitioner holds a valid federal controlled substance registry number.

(25) ~~(20)~~ "Prescription" means and includes an order for drugs or medicinal supplies written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs or medicinal supplies, issued in good faith and in the course of professional practice, intended to be filled, compounded, or dispensed by another person licensed by the laws of the state to do so, and meeting the requirements of s. 893.04. The term also includes an order for drugs or medicinal supplies so transmitted or written by a physician, dentist, veterinarian, or other practitioner licensed to practice in a state other than Florida, but only if the pharmacist called upon to fill such an order determines, in the exercise of his or her professional judgment, that the order was issued pursuant to a valid patient-physician relationship, that it is authentic, and that the drugs or medicinal supplies so ordered are considered necessary for the continuation of treatment of a chronic or recurrent illness. However, if the physician writing the prescription is not known to the pharmacist, the pharmacist shall obtain proof to a reasonable certainty of the validity of said prescription. A prescription order for a controlled substance shall not be issued on the same prescription blank with another prescription order for a controlled substance which is named or described in a different schedule, nor shall any prescription order for a controlled substance be issued on the same prescription blank as a prescription order for a medicinal drug, as defined in s.

465.031(5), which does not fall within the definition of a controlled substance as defined in this act.

(26) "Residential property" means a dwelling unit used, or intended for use, by an individual or individuals as a permanent residence. The term includes improved real property of between one and four dwellings; a condominium unit, as defined in s. 718.103(27); a cooperative unit, as defined in s. 719.103(24); or a mobile home or manufactured home, as defined in s. 320.01(2). The term does not include a hotel, motel, campground, marina, or timeshare unit.

(27) ~~(21)~~ "Wholesaler" means any person who acts as a jobber, wholesale merchant, or broker, or an agent thereof, who sells or distributes for resale any drug as defined by the Florida Drug and Cosmetic Act. However, this definition does not apply to persons who sell only patent or proprietary preparations as defined in the Florida Pharmacy Act. Pharmacies, and pharmacists employed thereby, are specifically excluded from this definition.

Section 2. Section 893.121, Florida Statutes, is created to read:

893.121 Quarantine of a clandestine laboratory.--

(1) The purpose of the quarantine provided for in this section is to prevent exposure of any person to the hazards associated with clandestine laboratory activities and provide protection from unsafe conditions that pose a threat to the public health, safety, and welfare. The department has the authority to quarantine residential property under s. 381.0011.

(2) Whenever a sheriff, police officer, or other law enforcement entity secures evidence from a residential property in which illegal clandestine laboratory activities occurred, the department must quarantine the property. The local law

enforcement entity securing evidence shall enforce a quarantine on the residential property as part of its duty to assist the department under s. 381.0012(5). Enforcement does not require the 24-hour posting of law enforcement personnel. The residential property shall remain quarantined until the department receives a certificate of fitness documenting that the property was decontaminated as defined by the department pursuant to s. 893.123 or demolished in accordance with s. 893.122(1), or a court order is presented requiring the quarantine to be lifted.

(3) The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 to establish a uniform notice to post at the site of a quarantined clandestine laboratory and a uniform letter of notification of the quarantine to be sent to the residential property owner or manager. It is the responsibility of local law enforcement to post the notice of a quarantine on the residential property, and it is the responsibility of the department to mail the letter of notification. The material in the letter and notice shall include, but not be limited to:

(a) That the residential property has been quarantined and a clandestine laboratory was seized on or inside the residential property.

(b) The date of the quarantine.

(c) The name and contact telephone number of the law enforcement entity posting the quarantine.

(d) A statement specifying that hazardous substances, toxic chemicals, or other hazardous waste products may have been present and may remain on or inside the residential property and that exposure to the substances may be harmful and may pose a threat to public health and the environment.

(e) A statement that it is unlawful for an unauthorized person to enter the contaminated residential property and that the removal of any notice of the quarantine is a second degree misdemeanor under s. 381.0025(1).

(f) A statement, in the notification letter, explaining how to have the quarantine lifted.

(4) Upon securing evidence from a residential property in which illegal clandestine laboratory activities occurred, the local law enforcement entity shall immediately notify the local health officer and the department's Division of Environmental Health that a residential property is quarantined and shall provide the name and contact information of the law enforcement entity, the name of the residential property owner or residential property manager, and the address of the property.

(5) To the extent possible, the department shall mail the letter of notification to the residential property owner or the manager of the residential property within 5 working days from the date of quarantine notifying the owner or manager that a clandestine laboratory was found on the property and that the property has been quarantined. The department shall also include a list of contamination assessment specialists and decontamination specialists and any other information deemed appropriate by the department to the residential property owner or manager.

(6) Any person who has an interest in a residential property that is quarantined pursuant to this section may file a petition in the circuit court in which the residential property is located to request a court order that the quarantine of the residential property be lifted for one of the following reasons:

(a) The residential property was wrongfully quarantined; or

(b) The residential property has been properly decontaminated as defined by the department pursuant to s. 893.123 or demolished pursuant to s. 893.122(1) and may be reoccupied for habitation, but the department refuses or fails to lift the quarantine.

(7) No person shall inhabit a quarantined residential property, offer the residential property to the public for temporary or indefinite habitation, or remove any notice of the quarantine. Any person who willfully violates a provision of this subsection commits a second degree misdemeanor under s. 381.0025(1).

Section 3. Section 893.122, Florida Statutes, is created to read:

893.122 Option of demolition; immunity from liability from health-based civil actions.--

(1) A residential property owner shall, upon notification from a law enforcement entity that clandestine laboratory activities have occurred in a property owned by that owner and that the property is quarantined, meet the decontamination standards as defined by the department pursuant to s. 893.123 unless the property owner, at the owner's discretion, elects to demolish the contaminated residential property. The demolition and removal of materials must meet the requirements of the Occupational Safety and Health Administration and the United States Environmental Protection Agency regulations pertaining to the generation, storage, transport, and disposal of hazardous wastes and any state or local requirements.

(2) A residential property owner who has met the decontamination standards, as evidenced by a certificate of fitness and a letter of reoccupancy pursuant to s.893.123, or has demolished the residential property in compliance with

subsection (1), shall have immunity from health-based civil actions brought by any future owner, renter, or other person who occupies such residential property, or a neighbor of such residential property, in which the alleged cause of the injury or loss is the existence of the clandestine laboratory. However, a person with a conviction, as defined in s. 944.607, for the manufacture of any substance regulated under this chapter on the residential property where clandestine laboratory activities occurred shall not have the immunity provided in this subsection.

Section 4. Section 893.123, Florida Statutes, is created to read:

893.123 Clandestine laboratory decontamination standards, certificate of fitness, and letter of reoccupancy.--

(1) The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 that establish:

(a) Standards for indoor air quality regarding levels of contaminants produced by clandestine laboratory activities to include methamphetamine, lead, mercury, and volatile organic compounds. These standards must be consistent with values commonly used by other states or comply with national standards.

(b) Standards for the cleanup and testing of clandestine laboratories.

(c) A certificate of fitness that shall act as appropriate documentation that a residential property has been decontaminated in accordance with specified standards. The certificate of fitness shall be submitted to the department by a contamination assessment specialist. The certificate of fitness shall include, but is not limited to:

1. The name of the residential property owner, the mailing and street address of the residential property owner, and, if

applicable, the parcel identification of the residential property.

2. The dates the residential property was quarantined and cleanup was completed.

3. A summary of the indoor air quality test results, findings, and conclusions as determined by a contamination assessment specialist.

4. The name and address of the contamination assessment specialist.

5. The name and address of the decontamination specialist.

6. The method of repair, replacement, or decontamination of the residential property.

(d) A letter of reoccupancy that will notify the residential property owner that the property may be reoccupied for habitation.

(2) Upon receipt of the certificate of fitness, the department shall send a letter of reoccupancy to the residential property owner or manager and to the local law enforcement entity that enforced the quarantine and posted the notice. The letter of reoccupancy must include the address of the residential property, a statement that the quarantine is lifted, and a statement that the residential property may be reoccupied for habitation.

(3) In the case of demolition, the department shall lift the quarantine on a residential property upon receipt of a letter presented by a demolition company stating that the quarantined property was demolished. The letter must include the address of the residential property and a statement that the demolition was performed in accordance to the requirements in s. 893.122(1).

Section 5. Section 893.124, Florida Statutes, is created to read:

893.124 Decontamination and contamination assessment specialists.--

(1)(a) The department shall compile and maintain lists of decontamination and contamination assessment specialists. The lists shall be posted on the department's Internet website. The department shall indicate on the website whether the specialists are bonded and insured.

(b) Persons authorized to perform decontamination or contamination assessments must have knowledge and skill in the handling of toxic substances. The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 specifying the requirements for persons authorized to perform decontamination and contamination assessments. Decontamination specialists shall be responsible for ensuring that all hazardous substances, toxic chemicals, or other hazardous waste products that may have been present are removed from the residential property and disposed of in accordance with federal, state, and local laws and regulations.

(2) In determining the level of contamination in a clandestine laboratory, the decontamination or contamination assessment specialist may request copies of any available law enforcement reports or information relating to the following:

(a) The length of time the residential property was used as a clandestine laboratory.

(b) The extent to which the residential property was exposed to chemicals used in clandestine laboratory activities.

(c) The chemical processes that were involved in the clandestine laboratory activities.

(d) The chemicals that were removed from the residential property.

(e) The location of the clandestine laboratory activities in relation to the habitable areas of the residential property.

(3) If the contamination assessment specialist determines that the residential property is not contaminated, the contamination assessment specialist shall prepare a certificate of fitness and submit the certificate to the department.

Section 6. Paragraph (s) of subsection (1) of section 465.016, Florida Statutes, is amended to read:

465.016 Disciplinary actions.--

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(s) Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02~~(20)~~ when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship.

Section 7. Paragraph (e) of subsection (1) of section 465.023, Florida Statutes, is amended to read:

465.023 Pharmacy permittee; disciplinary action.--

(1) The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline any pharmacy permittee who has:

(e) Dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02~~(20)~~ when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical

examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

Section 8. Paragraph (c) of subsection (1) of section 856.015, Florida Statutes, is amended to read:

856.015 Open house parties.--

(1) Definitions.--As used in this section:

(c) "Drug" means a controlled substance, as that term is defined in ss. 893.02~~(4)~~ and 893.03.

Section 9. Subsection (6) of section 893.135, Florida Statutes, is amended to read:

893.135 Trafficking; mandatory sentences; suspension or reduction of sentences; conspiracy to engage in trafficking.--

(6) A mixture, as defined in s. 893.02~~(14)~~, containing any controlled substance described in this section includes, but is not limited to, a solution or a dosage unit, including but not limited to, a pill or tablet, containing a controlled substance. For the purpose of clarifying legislative intent regarding the weighing of a mixture containing a controlled substance described in this section, the weight of the controlled substance is the total weight of the mixture, including the controlled substance and any other substance in the mixture. If there is more than one mixture containing the same controlled substance, the weight of the controlled substance is calculated by aggregating the total weight of each mixture.

Section 10. Paragraph (a) of subsection (1) of section 944.47, Florida Statutes, is amended to read:

944.47 Introduction, removal, or possession of certain articles unlawful; penalty.--

(1)(a) Except through regular channels as authorized by the officer in charge of the correctional institution, it is unlawful to introduce into or upon the grounds of any state correctional institution, or to take or attempt to take or send or attempt to send therefrom, any of the following articles which are hereby declared to be contraband for the purposes of this section, to wit:

1. Any written or recorded communication or any currency or coin given or transmitted, or intended to be given or transmitted, to any inmate of any state correctional institution.

2. Any article of food or clothing given or transmitted, or intended to be given or transmitted, to any inmate of any state correctional institution.

3. Any intoxicating beverage or beverage which causes or may cause an intoxicating effect.

4. Any controlled substance as defined in s. 893.02~~(4)~~ or any prescription or nonprescription drug having a hypnotic, stimulating, or depressing effect.

5. Any firearm or weapon of any kind or any explosive substance.

Section 11. Subsection (1) of section 951.22, Florida Statutes, is amended to read:

951.22 County detention facilities; contraband articles.--

(1) It is unlawful, except through regular channels as duly authorized by the sheriff or officer in charge, to introduce into or possess upon the grounds of any county detention facility as defined in s. 951.23 or to give to or receive from any inmate of any such facility wherever said inmate is located at the time or to take or to attempt to take or send therefrom any of the following articles which are hereby

declared to be contraband for the purposes of this act, to wit: Any written or recorded communication; any currency or coin; any article of food or clothing; any tobacco products as defined in s. 210.25(11); any cigarette as defined in s. 210.01(1); any cigar; any intoxicating beverage or beverage which causes or may cause an intoxicating effect; any narcotic, hypnotic, or excitative drug or drug of any kind or nature, including nasal inhalators, sleeping pills, barbiturates, and controlled substances as defined in s. 893.02~~(4)~~; any firearm or any instrumentality customarily used or which is intended to be used as a dangerous weapon; and any instrumentality of any nature that may be or is intended to be used as an aid in effecting or attempting to effect an escape from a county facility.

Section 12. Paragraph (a) of subsection (1) of section 985.4046, Florida Statutes, is amended to read:

985.4046 Introduction, removal, or possession of certain articles unlawful; penalty.--

(1)(a) Except as authorized through program policy or operating procedure or as authorized by the facility superintendent, program director, or manager, a person may not introduce into or upon the grounds of a juvenile detention facility or commitment program, or take or send, or attempt to take or send, from a juvenile detention facility or commitment program, any of the following articles, which are declared to be contraband under this section:

1. Any unauthorized article of food or clothing.

2. Any intoxicating beverage or any beverage that causes or may cause an intoxicating effect.

3. Any controlled substance, as defined in s. 893.02~~(4)~~, or any prescription or nonprescription drug that has a hypnotic, stimulating, or depressing effect.

4. Any firearm or weapon of any kind or any explosive substance.

Section 13. This act shall take effect July 1, 2006.

========== T I T L E A M E N D M E N T ==========

Remove the entire title and insert:

A bill to be entitled

An act relating to clandestine laboratory contamination; amending s. 893.02, F.S.; providing definitions; creating s. 893.121, F.S.; providing for quarantine of any residential property where illegal clandestine laboratory activities occurred; providing for establishment of a uniform notice and a uniform letter of notification; providing for posting of specified notice at the site of a quarantine; providing requirements for the sending of a specified letter of notification to a residential property owner or manager; providing for petitions by certain persons in circuit court to lift such quarantines under certain conditions; prohibiting specified violations relating to such quarantines; creating s. 893.122, F.S.; permitting demolition of quarantined residential property under certain conditions; providing immunity from health-based civil actions for residential property owners who have met specified clandestine laboratory decontamination standards as evidenced by specified documentation; providing an exception to such immunity for persons convicted of manufacturing controlled substances at the site; creating s. 893.123, F.S.; providing for rulemaking to adopt clandestine laboratory decontamination standards; providing for certificates of fitness to indicate that

decontamination has been completed; providing requirements for the lifting of a quarantine upon demolition of the property; creating s. 893.124, F.S.; requiring the Department of Health to specify requirements for persons authorized to perform decontamination and contamination assessments; requiring the department to compile and maintain lists of decontamination and contamination assessment specialists; providing responsibilities for decontamination specialists; permitting decontamination and contamination assessment specialists to request specified documents; providing for the issuance of certificates of fitness by contamination assessment specialists; amending ss. 465.016, 465.023, 856.015, 893.135, 944.47, 951.22, and 985.4046, F.S.; conforming cross-references; providing an effective date.

WHEREAS, methamphetamine use and production is increasing throughout the state, and

WHEREAS, in places where methamphetamine production has occurred, significant levels of chemical contamination may be found, especially in residential properties when the contamination is not decontaminated, and

WHEREAS, children are susceptible to environmental toxicants via the skin, and the ingestion of residual methamphetamine is considered to be a result of hand-to-mouth activities, and

WHEREAS, studies on methamphetamine use during pregnancy showed an increased incidence of intrauterine growth retardation, prematurity, and perinatal complications, and

WHEREAS, once clandestine laboratories have been seized, the public may continue to be harmed by the illegal dumping of

chemical byproducts and the chemical residues that remain on the residential property, and

WHEREAS, there are no statewide standards for determining when a site of a seized clandestine laboratory has been successfully decontaminated, and

WHEREAS, the Legislature finds that this act is necessary for the immediate preservation of the public health, safety, and welfare and fulfills an important state interest, NOW, THEREFORE,

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 411 Psychotherapist-Patient Privilege
SPONSOR(S): Roberson
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Judiciary Committee	14 Y, 0 N	Hogge	Hogge
2) Health Care Regulation Committee		Hamrick	Mitchell
3) Justice Council			
4)			
5)			

SUMMARY ANALYSIS

HB 411 extends the psychotherapist-patient privilege to advanced registered nurse practitioners whose primary scope of practice is the diagnosis or treatment of mental or emotional conditions, including chemical abuse. Advanced registered nurse practitioners are persons licensed to practice professional nursing and certified in advanced or specialized nursing practice.

The Florida Evidence Code includes a number of privileges. Privileges render certain communications or records inadmissible as evidence. One such privilege under Florida law is the psychotherapist-patient privilege. This privilege makes communications between psychotherapists and their patients for the purpose of diagnosing or treating mental or emotional health conditions inadmissible as evidence.

The Legislature has on various occasions expanded the definition of "psychotherapist" to include other practitioners. Currently, "psychotherapist" includes licensed medical doctors, psychologists, clinical social workers, marriage and family therapists, and mental health counselors. Also included are other treatment personnel employed by certain licensed health facilities and engaged primarily in the diagnosis and treatment of mental health and substance abuse conditions.

Fiscal Impact: The bill does not appear to have a fiscal impact on state or local government.

The bill takes effect on July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Safeguard individual liberty-The bill could be seen as safeguarding individual liberty by expanding the protections given to certain communications between patients and their mental health professionals.

B. EFFECT OF PROPOSED CHANGES:

This bill extends the psychotherapist-patient privilege to advanced registered nurse practitioners whose primary scope of practice is the diagnosis or treatment of mental or emotional conditions, including chemical abuse. Advanced registered nurse practitioners are persons licensed to practice professional nursing and certified in advanced or specialized nursing practice. Many advanced nurse practitioners are already included within the current definition of "psychotherapist," and enjoy the privilege as staff of a licensed hospital, mental health facility or substance abuse center.

PRESENT SITUATION

Psychotherapist-Patient Privilege

The Florida Evidence Code contains a number of privileges.[1] Privileges render certain communications or records within a protected relationship inadmissible as evidence in civil and criminal proceedings.

Examples of protected relationships include:

- The relationship between attorney and client;
- Clergy and penitent; and
- Husband and wife.

Another is the psychotherapist-patient privilege. This privilege makes communications between psychotherapists and their patients for the purpose of diagnosing or treating mental or emotional health conditions inadmissible as evidence.

Concerning the psychotherapist-patient privilege, the operative language in the Code provides:

> A patient has a privilege to refuse to disclose, and to prevent any other person from disclosing, confidential communications or records made for the purpose of diagnosis or treatment of the patient's mental or emotional condition, including alcoholism and other drug addiction, between the patient and the psychotherapist, or persons who are participating in the diagnosis or treatment under the direction of the psychotherapist.[2]

This privilege includes any diagnosis made, and advice given, by the psychotherapist in the course of that relationship.

The privilege has been extended to various mental health professionals since first incorporated into the Code. Initially limited to psychiatrists, the Legislature has extended the privilege to any person licensed or certified as a psychologist, clinical social worker, marriage and family therapist, or mental health counselor under Florida law and laws of any other state or, as applicable, any nation, and who is engaged in the diagnosis or treatment of a mental or emotional condition.

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[1] See Chapter 90, F.S.
[2] See s. 90.503(2), F.S.

Later, the Legislature extended it to cover treatment personnel of state-licensed hospitals, mental health facilities and substance abuse treatment centers, when those personnel are primarily engaged in mental health diagnosis or treatment; and state-licensed or certified social workers, marriage and family therapists, and mental health counselors, again, only if primarily engaged in mental health treatment or diagnosis.

Florida's psychotherapist-patient privilege may be asserted by the patient, by a guardian or conservator of the patient, or by the personal representative of the estate of a deceased patient. It may also be asserted by the psychotherapist, but only on the patient's behalf. An assertion of the privilege by the psychotherapist creates a rebuttable presumption that it is made on the patient's behalf.

Advanced Registered Nurse Practitioners

Nursing in Florida is regulated under the Nurse Practice Act, chapter 464, F.S. Under the Nurse Practice Act, nurses licensed in Florida may seek certification as advanced registered nurse practitioners. With this certification, they may "perform acts of medical diagnosis and treatment, prescription, and operation which are identified by" a joint committee of the Board of Nursing and the Board of Medicine.

Advanced registered nurse practitioners perform all duties of a registered nurse, in addition to advanced level nursing in accordance with established protocols, including managing selected medical problems, monitoring and altering drug therapies, initiating appropriate therapies for certain conditions, performing physical examinations, ordering and evaluating diagnostic tests, ordering physical and occupational therapy, and initiating and monitoring therapies for certain uncomplicated acute illnesses.

Advanced registered nurse practitioners may perform medical acts under the general supervision of a medical physician, osteopathic physician, or dentist within the framework of standing protocols identifying the medical acts to be performed and the conditions for their performance.[3] Although advanced registered nurse practitioners may prescribe medications in accordance with a protocol, they cannot prescribe controlled substances.

To be certified as an advanced registered nurse practitioner, a nurse must demonstrate one of the following:

- Successful completion of a course in advanced nursing which is at least one academic year in length and primarily meant to prepare nurses for advanced or specialized practice;
- Certification by an appropriate specialty board; or
- Graduation from a program leading to a master's degree in a nursing clinical area.

C. SECTION DIRECTORY:

Section 1. Amends s. 90.503, F.S., to add advanced registered nurse practitioners with a certain scope of practice to the definition of "psychotherapist" for purposes of the application of the psychotherapist-patient privilege.
Section 2. Provides an effective date of July 1, 2006.

[3] See s. 464.003 (3)(c), F.S.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is required to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to psychotherapist-patient privilege; amending s. 90.503, F.S.; redefining the term "psychotherapist" to include certain advanced registered nurse practitioners for purposes of the psychotherapist-patient privilege of the Florida Evidence Code; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (a) of subsection (1) of section 90.503, Florida Statutes, is amended to read:

90.503 Psychotherapist-patient privilege.--

(1) For purposes of this section:

(a) A "psychotherapist" is:

1. A person authorized to practice medicine in any state or nation, or reasonably believed by the patient so to be, who is engaged in the diagnosis or treatment of a mental or emotional condition, including alcoholism and other drug addiction;

2. A person licensed or certified as a psychologist under the laws of any state or nation, who is engaged primarily in the diagnosis or treatment of a mental or emotional condition, including alcoholism and other drug addiction;

3. A person licensed or certified as a clinical social worker, marriage and family therapist, or mental health counselor under the laws of this state, who is engaged primarily in the diagnosis or treatment of a mental or emotional

condition, including alcoholism and other drug addiction; ~~or~~

4. Treatment personnel of facilities licensed by the state pursuant to chapter 394, chapter 395, or chapter 397, of facilities designated by the Department of Children and Family Services pursuant to chapter 394 as treatment facilities, or of facilities defined as community mental health centers pursuant to s. 394.907(1), who are engaged primarily in the diagnosis or treatment of a mental or emotional condition, including alcoholism and other drug addiction; or~~.~~

5. An advanced registered nurse practitioner certified under s. 464.012, whose primary scope of practice is the diagnosis or treatment of mental or emotional conditions, including chemical abuse, and limited only to actions performed in accordance with part I of chapter 464.

Section 2. This act shall take effect July 1, 2006.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 439 Certificate of Birth Resulting in Stillbirth
SPONSOR(S): Planas and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 746

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell AJB	Mitchell
2) Governmental Operations Committee			
3) Health Care Appropriations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

HB 439 creates a new section of law to allow parents of a stillborn to obtain a "Certificate of Birth Resulting in Stillbirth." Stillbirth can be devastating to a woman and her family. Making available a Certificate of Birth Resulting in Stillbirth has been shown to help some families with the grieving and healing process. The funeral director, physician or other personnel filling out the fetal death Certificate will alert parents of a stillborn of the availability of a Certificate of Birth Resulting in Stillbirth.

Stillbirths occur in nearly 1 out of every 200 pregnancies. Estimates range from 25,000 to 39,000 stillbirths annually in the U.S. It is difficult to estimate an accurate count because national and state rates for "infant mortality" do not include stillborns. In the last 10 years there has been a nationalwide movement to increase the awareness of stillbirths and increase research.

The approximate fiscal impact of the bill in the first year is an expenditure of $4,097. There is a positive fiscal impact of $900 projected in year two.

The bill provides an effective date of July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill creates a "Certificate of Birth Resulting in Stillbirth" available through the Office of Vital Statistics within the Department of Health. The approximate fiscal impact of the bill in first year is an expenditure of $4,097. There is a positive fiscal impact of $900 projected in year two.

Empower Families – Stillbirth can be devastating to a woman and her family. Making available a Certificate of Birth Resulting in Stillbirth has been shown to help some families with the grieving and healing process.

B. EFFECT OF PROPOSED CHANGES:

HB 439 creates s. 382.0085, F.S., to establish a "Certificate of Birth Resulting in Stillbirth" available from the State Office of Vital Statistics. The bill amends s. 382.002, F.S., to define "Certificate of Birth Resulting in Stillbirth" as a certificate issued to record the birth of a stillborn child, and "stillbirth" as an unintended, intrauterine death after gestational age of not less than 20 completed weeks. A "Certificate of Birth Resulting in Stillbirth" is created in the Office of Vital Statistics.

How to Obtain a Certificate of Birth Resulting in Stillbirth

The bill specifies that the person[1] required to file a fetal death Certificate will advise the parent of a stillborn child that they have the option to obtain a "Certificate of Birth Resulting in Stillbirth." Parents are also to be advised where they can obtain the Certificate and how to contact the Office of Vital Statistics. To order a Certificate of Birth Resulting in Stillbirth a parent may provide the following information to the Office of Vital Statistics:

- a name for the stillborn child,
- date of the event, and
- the county in which the event occurred.

The name provided on the Certificate of Birth Resulting in Stillbirth must match the name provided on the Certificate of Fetal Death. If there is no name provided on the Certificate of Fetal Death, the Office of Vital Statistics will fill in the first name as "baby boy" or "baby girl" and the last name as the last name of the parent. Parents may request a Certificate of Birth Resulting in Stillbirth regardless of the date on which the Certificate of Fetal Death was issued. The Certificate may only be issued to the parents of a stillborn child.[2]

Certificate of Birth Resulting in Stillbirth Requirements

The Certificate of Birth Resulting in Stillbirth must include the state file number of the corresponding Certificate of Fetal Death. The bill also requires that the Certificate must contain the statement "This Certificate is not proof of live birth" and subsequently, the Office of Vital Statistics may not use the Certificate of Birth Resulting in Stillbirth to calculate live births.

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[1] The funeral director, physician, or other personnel are responsible for filling out the fetal death certificate.

[2] Under the proposed legislation a refusal by the Office of Vital Statistics to issue a certificate to a person who is not entitled to a certificate of birth resulting in stillbirth constitutes a final agency action and is not subject to review under Chapter 120, F.S.

The bill directs the Department of Health (DOH) to prescribe by rule the form and content of a Certificate of Birth Resulting in Stillbirth. The department is required to specify the information necessary to prepare the Certificate by September 1, 2006.

HB 439 amends s. 382.0255, F.S., to allow the Office of Vital Statistics to charge a fee for a Certificate of Birth Resulting in Stillbirth.

The bill provides an effective date of July 1, 2006.

CURRENT SITUATION

Office of Vital Statistics

Currently the Office of Vital Statistics does not issue Certificates of Birth Resulting in Stillbirth. Under s. 382.008, F.S., the Office recognizes stillbirths as fetal deaths and issues Certificates of Fetal Death. A fetal death is defined as:

> *"death prior to the complete expulsion and extraction of a product of human conception from its mother if the 20th week of gestation has been reached and the death is indicated by the fact that after such expulsion or extraction the fetus does not breathe or show any other evidence of life such as the beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles."*

The Certificate of Fetal Death must be filed within 5 days after the death and prior to final disposition. Most often the funeral director fills out the Fetal Death Certificate.[3] In the absence of a funeral director, the physician or other person in attendance shall file a Death or Fetal Death Certificate. Under the proposed legislation this person would be responsible for informing the parents of the stillborn child that a Certificate of Birth Resulting in Stillbirth is available to them through the Office of Vital Statistics.

The Office of Vital Statistics collects statewide data on live births, deaths, fetal deaths, marriages, divorces, and name changes. Under the proposed legislation stillborns would still be classified as a fetal death, but the parents would have the option of requesting a "Certificate of Birth Resulting in Stillbirth."

BACKGROUND

Stillbirth

When fetal death occurs after 20 weeks of pregnancy, it is referred to as stillbirth. Over the last 20 years, stillbirths have declined by nearly 50 percent. This is largely due to better treatment of certain conditions, such as maternal high blood pressure and diabetes, which can increase the risk of stillbirth. Rh disease,[4] which until 1960s was an important cause of stillbirth, can now usually be prevented.

However, stillbirths still occur in nearly 1 out of every 200 pregnancies.[5] Estimates range from 25,000 to 39,000 stillbirths annually in the U.S. It is difficult to estimate an accurate count because national and state rates for "infant mortality" do not include stillborns. In the last 10 years there has been a national movement to increase the awareness of stillbirths and increase research. To support more research The National Institute of Child Health and Human Development (NICHD) created the initiative, *Research on the Scope and Causes of Stillbirth in the United States*. The NICHD project developed a network of research sites whole sole purpose is to understand stillbirth.

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[3] 382.008, F.S. and 64V-1.007, F.A.C.

[4] Rh disease is the incompatibility between the blood of the mother and baby. It is treated by giving an Rh-negative woman an injection of immune globulin at 28 weeks of pregnancy, and again after the birth of an Rh-positive baby.

[5] National Institute of Health, Stillbirth Facts, http://nichd.nih.gov/womenshealth/miscarriage.cfm

Up to half of all stillbirths occur in pregnancies that seem problem-free. While 14 percent of fetal deaths occur during labor and delivery, 86 percent occur before labor begins. The pregnant woman may suspect something is wrong if the baby suddenly stops moving around and kicking. The most common causes of stillbirth include: placental problems, birth defects, growth restrictions, and infections. Still in more than one-third of cases the cause of stillbirth cannot be determined.

Stillbirth Policy Trends

Currently there is a national movement to recognize the birth of stillborn children. Thirteen states have passed legislation that creates a "Certificate of Birth Resulting in Stillbirth." Another nine states passed laws to create a "Certificate of Stillbirth." Stillborn awareness advocates prefer the former Certificate because it recognizes that a birth has taken place.[6]

C. SECTION DIRECTORY:

Section 1. Amends s. 382.002, F.S., to provide definitions for "Certificate of Birth Resulting in Stillbirth" and "stillbirth."

Section 2. Creates s. 382.0085, F.S., to provide for stillbirth registration.

Section 3. Amends s. 382.0255, F.S., to allow the Department of Health to charge a fee for a Certificate of Birth Resulting in Stillbirth.

Section 4. Provides an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

	1st Year	2nd Year
Estimated Revenue	$603	$900
For 2005, vital statistics issued 67 fetal death certifications statewide.		
Total Estimated Revenue	**$603**	**$900**

2. Expenditures:

	1st Year	2nd Year (Annualized/Recurr.)
Estimated Expenditures		
Salaries	0	0
Expense		
Forms design/printing cost	$ 1,200	0
Computer system modifications	$ 3,500	0
Total Estimated Expenditures	**$ 4,700**	**0**

[6] Missing Angels Foundation, legislation state chart, http://www.missfoundation.org.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The Office of Vital Statistics is authorized to charge a fee for a Certificate of Birth Resulting in Stillbirth. Parents of stillborn children must pay this nominal fee to obtain a Certificate.[7]

D. FISCAL COMMENTS:

According to the Department of Health, there will be a minimal fiscal impact associated with the development of the certification, applications and modifications to Office of Vital Statistics computer system. The bill authorizes the department to charge a fee for the certifications which should over time offset the costs the department will encounter. Currently less than 1800 fetal deaths are filed annually. In 2005, there were 67 requests for certifications of fetal deaths.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

[See C. DRAFTING ISSUES OR OTHER COMMENTS]

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill directs the Department of Health to promulgate rules regarding the form and content of a Certificate of Birth Resulting in Stillbirth and specify the information necessary to prepare the Certificate by September 1, 2006. Chapter 120, F.S., the Administrative Procedures Act, requires that rules are promulgated within 180 days after the effective date of bill. The effective day of the bill is July 1, 2006 allowing only 62 days for the Department of Health to complete the rulemaking process. The Department of Health may not be able to promulgate rules within the 2 month time frame specified in the bill.

The bill sponsor intends to file an amendment to remedy the drafting issue.

[7] The Department of Health may charge $3-$5 for the retrieval of records and $3-$5 to photocopy records. Additional fees of $1-$2, up to a maximum total of $50, are charged for additional calendar years of records searched or retrieved.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to certificate of birth resulting in stillbirth; amending s. 382.002, F.S.; providing definitions; creating s. 382.0085, F.S.; requiring that the person required to file the fetal death certificate advise a parent of a stillborn child about the availability of a certificate of birth resulting in stillbirth; authorizing the parent to name the stillborn child on a certificate; requiring a state file number for the certificate; requiring the Department of Health to prescribe the form and content of the certificate by rule; prohibiting the Office of Vital Statistics within the Department of Health from using a certificate of birth resulting in stillbirth to calculate certain statistics; authorizing a parent to request a certificate of birth resulting in stillbirth without regard to the date on which the certificate of fetal death was issued; prohibiting certain persons from obtaining a certificate of birth resulting in stillbirth; authorizing the Office of Vital Statistics to charge a fee; requiring a certificate of birth resulting in stillbirth to contain certain information; requiring the department to adopt rules; amending s. 382.0255, F.S.; authorizing the department to collect fees for a search or retrieval of a certificate of birth resulting in stillbirth; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 382.002, Florida Statutes, is amended to read:

382.002 Definitions.--As used in this chapter, the term:

(1) "Certificate of birth resulting in stillbirth" means a certificate issued to record the birth of a stillborn child.

(2) ~~(1)~~ "Certification" or "certified" means a document containing all or a part of the exact information contained on the original vital record, and which, when issued by the State Registrar, has the full force and effect of the original vital record.

(3) ~~(2)~~ "Dead body" means a human body or such parts of a human body from the condition of which it reasonably may be concluded that death recently occurred.

(4) ~~(3)~~ "Department" means the Department of Health.

(5) ~~(4)~~ "Dissolution of marriage" includes an annulment of marriage.

(6) ~~(5)~~ "Fetal death" means death prior to the complete expulsion or extraction of a product of human conception from its mother if the 20th week of gestation has been reached and the death is indicated by the fact that after such expulsion or extraction the fetus does not breathe or show any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.

(7) ~~(6)~~ "Final disposition" means the burial, interment, cremation, removal from the state, or other authorized disposition of a dead body or a fetus as described in subsection (6) ~~(5)~~. In the case of cremation, dispersion of ashes or

cremation residue is considered to occur after final disposition; the cremation itself is considered final disposition.

(8) ~~(7)~~ "Funeral director" means a licensed funeral director or direct disposer licensed pursuant to chapter 497 or other person who first assumes custody of or effects the final disposition of a dead body or a fetus as described in subsection (6) ~~(5)~~.

(9) ~~(8)~~ "Legal age" means a person who is not a minor, or a minor who has had the disability of nonage removed as provided under chapter 743.

(10) ~~(9)~~ "Live birth" means the complete expulsion or extraction of a product of human conception from its mother, irrespective of the duration of pregnancy, which, after such expulsion, breathes or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord, and definite movement of the voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached.

(11) ~~(10)~~ "Medical examiner" means a person appointed pursuant to chapter 406.

(12) ~~(11)~~ "Physician" means a person authorized to practice medicine, osteopathic medicine, or chiropractic medicine pursuant to chapter 458, chapter 459, or chapter 460.

(13) ~~(12)~~ "Registrant" means the child entered on a birth certificate, the deceased entered on a death certificate, and the husband or wife entered on a marriage or dissolution of marriage record.

(14) "Stillbirth" means an unintended, intrauterine fetal

death after a gestational age of not less than 20 completed weeks.

(15) ~~(13)~~ "Vital records" or "records" means certificates or reports of birth, death, fetal death, marriage, dissolution of marriage, name change filed pursuant to s. 68.07, and data related thereto.

(16) ~~(14)~~ "Vital statistics" means a system of registration, collection, preservation, amendment, and certification of vital records, the collection of other reports required by this act, and activities related thereto, including the tabulation, analysis, and publication of data obtained from vital records.

Section 2. Section 382.0085, Florida Statutes, is created to read:

382.0085 Stillbirth registration.--

(1) The person who is required to file a fetal death certificate under this chapter shall advise the parent of a stillborn child:

(a) That the parent may request the preparation of a certificate of birth resulting in stillbirth;

(b) That the parent may obtain a certificate of birth resulting in stillbirth by contacting the Office of Vital Statistics; and

(c) How the parent may contact the Office of Vital Statistics to request a certificate of birth resulting in stillbirth.

(2) To order a certificate of birth resulting in a stillbirth, a parent may provide a name for a stillborn child,

the date of the event, and the county in which the event occurred on the request for a certificate of birth resulting in stillbirth. If a name does not appear on the fetal death certificate and the requesting parent does not wish to provide a name, the Office of Vital Statistics shall fill in the certificate with the name "baby boy" or "baby girl" and the last name of the parent. The name of the stillborn child provided on or later added by amendment to the certificate of birth resulting in stillbirth must be the same name as placed on the original or amended certificate of the fetal death report pursuant to s. 382.008.

(3) A certificate of birth resulting in stillbirth must include the state file number of the corresponding certificate of fetal death.

(4) By September 1, 2006, the department shall prescribe by rule the form and content of a certificate of birth resulting in stillbirth and shall specify the information necessary to prepare the certificate.

(5) The Office of Vital Statistics may not use a certificate of birth resulting in stillbirth to calculate live birth statistics.

(6) A parent may request that the Office of Vital Statistics issue a certificate of birth resulting in stillbirth regardless of the date on which the certificate of fetal death was issued.

(7) A certificate of birth resulting in stillbirth may not be issued to any person other than a parent listed on the fetal death certificate. A refusal by the Office of Vital Statistics

to issue a certificate to a person who is not entitled to a certificate of birth resulting in stillbirth constitutes final agency action and is not subject to review under chapter 120.

(8) The Office of Vital Statistics may charge a fee for the certificate of birth resulting in stillbirth pursuant to s. 382.0255.

(9) A certificate of birth resulting in stillbirth must contain the statement "This certificate is not proof of a live birth."

(10) The department shall adopt rules to administer this section.

Section 3. Paragraph (a) of subsection (1) of section 382.0255, Florida Statutes, is amended to read:

382.0255 Fees.--

(1) The department is entitled to fees, as follows:

(a) Not less than $3 or more than $5 for the first calendar year of records searched or retrieved, including a certificate of birth resulting in stillbirth, and a computer certification of the record, a photocopy or birth card if a computer certification is not available, or, if a ~~no~~ record is not located, a certified statement to that effect. An additional fee of not less than $3 or more than $5 if a photocopy is requested in place of or in addition to a computer certification. Additional fees of not less than $1 or more than $2, up to a maximum total of $50, shall be charged for additional calendar years of records searched or retrieved.

Section 4. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 439**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Planas offered the following:

Amendment (with directory and title amendments)

Remove line(s) 107-110 and insert:

Statistics;

(c) How the parent may contact the Office of Vital Statistics to request a certificate of birth resulting in stillbirth; and

(d) That a copy of the original certificate of birth resulting in stillbirth is a document that is available as a public record when held by an agency as defined under s. 119.011(2).

========== T I T L E A M E N D M E N T ==========

Remove line(s) 8 and insert:

stillbirth; requiring that the person required to file the fetal death certificate inform a parent of a stillborn child that copies of the birth certificate resulting in stillbirth may be available as a public record; authorizing the parent to name the stillborn

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 2 (for drafter's use only)

Bill No. **HB 439**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation Committee

Representative(s) Planas offered the following:

Amendment

Remove line(s) 127 and insert:

(4) The department shall prescribe

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 3 (for drafter's use only)

Bill No. **HB 439**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Planas offered the following:

Amendment (with directory and title amendments)

Remove line(s) 138-140 and insert:

(7) Only a parent named on a fetal death certificate may request that the Office of Vital Statistics create a certificate of birth resulting in stillbirth. The Office of Vital Statistics must inform any parent who requests a certificate of birth resulting in stillbirth that a copy of the document is available as a public record when held by an agency as defined under s. 119.011(2). A refusal by the Office of Vital Statistics

========== T I T L E A M E N D M E N T ==========

Remove line(s) 18-19 and insert:

authorizing certain parents to request a certificate of birth resulting in stillbirth from the Office of Vital Statistics; requiring the Office of Vital Statistics to inform such parents that a copy of a certificate of birth resulting in stillbirth may be available as a public record; authorizing the Office

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 4 (for drafter's use only)

Bill No. HB 439

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation Committee

Representative(s) Sobel offered the following:

Amendment (with directory and title amendments)

Remove everything after the enacting clause and insert:

Section 1. Section 382.002, Florida Statutes, is amended to read:

382.002 Definitions.--As used in this chapter, the term:

(1) "Certificate of stillbirth" means a certificate issued to record the birth of a stillborn child.

(2) ~~(1)~~ "Certification" or "certified" means a document containing all or a part of the exact information contained on the original vital record, and which, when issued by the State Registrar, has the full force and effect of the original vital record.

(3) ~~(2)~~ "Dead body" means a human body or such parts of a human body from the condition of which it reasonably may be concluded that death recently occurred.

(4) ~~(3)~~ "Department" means the Department of Health.

(5) ~~(4)~~ "Dissolution of marriage" includes an annulment of marriage.

(6) ~~(5)~~ "Fetal death" means death prior to the complete expulsion or extraction of a product of human conception from its mother if the 20th week of gestation has been reached and the death is indicated by the fact that after such expulsion or extraction the fetus does not breathe or show any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.

(7) ~~(6)~~ "Final disposition" means the burial, interment, cremation, removal from the state, or other authorized disposition of a dead body or a fetus as described in subsection (6) ~~(5)~~. In the case of cremation, dispersion of ashes or cremation residue is considered to occur after final disposition; the cremation itself is considered final disposition.

(8) ~~(7)~~ "Funeral director" means a licensed funeral director or direct disposer licensed pursuant to chapter 497 or other person who first assumes custody of or effects the final disposition of a dead body or a fetus as described in subsection (6) ~~(5)~~.

(9) ~~(8)~~ "Legal age" means a person who is not a minor, or a minor who has had the disability of nonage removed as provided under chapter 743.

(10) ~~(9)~~ "Live birth" means the complete expulsion or extraction of a product of human conception from its mother, irrespective of the duration of pregnancy, which, after such expulsion, breathes or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord, and

definite movement of the voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached.

(11) ~~(10)~~ "Medical examiner" means a person appointed pursuant to chapter 406.

(12) ~~(11)~~ "Physician" means a person authorized to practice medicine, osteopathic medicine, or chiropractic medicine pursuant to chapter 458, chapter 459, or chapter 460.

(13) ~~(12)~~ "Registrant" means the child entered on a birth certificate, the deceased entered on a death certificate, and the husband or wife entered on a marriage or dissolution of marriage record.

(14) "Stillbirth" means an unintended, intrauterine fetal death after a gestational age of not less than 20 completed weeks.

(15) ~~(13)~~ "Vital records" or "records" means certificates or reports of birth, death, fetal death, marriage, dissolution of marriage, name change filed pursuant to s. 68.07, and data related thereto.

(16) ~~(14)~~ "Vital statistics" means a system of registration, collection, preservation, amendment, and certification of vital records, the collection of other reports required by this act, and activities related thereto, including the tabulation, analysis, and publication of data obtained from vital records.

Section 2. Section 382.0085, Florida Statutes, is created to read:

382.0085 Stillbirth registration.--

(1) The person who is required to file a fetal death certificate under this chapter shall advise the parent of a stillborn child:

(a) That the parent may request the preparation of a certificate of stillbirth;

(b) That the parent may obtain a certificate of stillbirth by contacting the Office of Vital Statistics; and

(c) How the parent may contact the Office of Vital Statistics to request a certificate of stillbirth.

(2) To order a certificate of birth resulting in a stillbirth, a parent may provide a name for a stillborn child, the date of the event, and the county in which the event occurred on the request for a certificate of stillbirth. If a name does not appear on the fetal death certificate and the requesting parent does not wish to provide a name, the Office of Vital Statistics shall fill in the certificate with the name "baby boy" or "baby girl" and the last name of the parent. The name of the stillborn child provided on or later added by amendment to the certificate of stillbirth must be the same name as placed on the original or amended certificate of the fetal death report pursuant to s. 382.008.

(3) A certificate of stillbirth must include the state file number of the corresponding certificate of fetal death.

(4) By September 1, 2006, the department shall prescribe by rule the form and content of a certificate of stillbirth and shall specify the information necessary to prepare the certificate.

(5) The Office of Vital Statistics may not use a certificate of stillbirth to calculate live birth statistics.

(6) A parent may request that the Office of Vital Statistics issue a certificate of stillbirth regardless of the date on which the certificate of fetal death was issued.

(7) A certificate of stillbirth may not be issued to any person other than a parent listed on the fetal death certificate. A refusal by the Office of Vital Statistics to issue a certificate to a person who is not entitled to a certificate of stillbirth constitutes final agency action and is not subject to review under chapter 120.

(8) The Office of Vital Statistics may charge a fee for the certificate of stillbirth pursuant to s. 382.0255.

(9) A certificate of stillbirth must contain the statement "This certificate is not proof of a live birth."

(10) The department shall adopt rules to administer this section.

Section 3. Paragraph (a) of subsection (1) of section 382.0255, Florida Statutes, is amended to read:

382.0255 Fees.--

(1) The department is entitled to fees, as follows:

(a) Not less than $3 or more than $5 for the first calendar year of records searched or retrieved, including a certificate of stillbirth, and a computer certification of the record, a photocopy or birth card if a computer certification is not available, or, if a ~~no~~ record is not located, a certified statement to that effect. An additional fee of not less than $3 or more than $5 if a photocopy is requested in place of or in addition to a computer certification. Additional fees of not less than $1 or more than $2, up to a maximum total of $50, shall be charged for additional calendar years of records searched or retrieved.

Section 4. This act shall take effect July 1, 2006.

========== T I T L E A M E N D M E N T ==========

Amendment No. 4 (for drafter's use only)

Remove the entire title and insert:

A bill to be entitled

An act relating to certificate of stillbirth; amending s. 382.002, F.S.; providing definitions; creating s. 382.0085, F.S.; requiring that the person required to file the fetal death certificate advise a parent of a stillborn child about the availability of a certificate of stillbirth; authorizing the parent to name the stillborn child on a certificate; requiring a state file number for the certificate; requiring the Department of Health to prescribe the form and content of the certificate by rule; prohibiting the Office of Vital Statistics within the Department of Health from using a certificate of stillbirth to calculate certain statistics; authorizing a parent to request a certificate of stillbirth without regard to the date on which the certificate of fetal death was issued; prohibiting certain persons from obtaining a certificate of stillbirth; authorizing the Office of Vital Statistics to charge a fee; requiring a certificate of stillbirth to contain certain information; requiring the department to adopt rules; amending s. 382.0255, F.S.; authorizing the department to collect fees for a search or retrieval of a certificate of stillbirth; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 523 Florida Center for Nursing
SPONSOR(S): Robaina
TIED BILLS: **IDEN./SIM. BILLS:** SB 480

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Hamrick	Mitchell
2) Colleges & Universities Committee			
3) Health Care Appropriations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

HB 523 revises the goals and board membership of the Florida Center for Nursing. It requires the Board of Nursing to survey nurses on workforce planning issues at licensure and renewal. The bill provides that $5 of every nurse licensure fee must be transferred to the Florida Center for Nursing Trust Fund to support, maintain and expand its goals.

The bill specifies that the survey information is to be collected by the Board of Nursing and provided to the Florida Center for Nursing for analysis and workforce planning. The Board of Nursing is prohibited from increasing licensure fees to implement the provisions of this bill. The bill expands the Center's goals to include the development of a survey. The bill does not specify the type of information to be gathered, a date for compliance, or identify projected outcomes.

Currently, all 16 members of the board of directors are appointed by the President of the Senate, the Speaker of the House, the Governor, and State Board of Education from recommendations made by key stakeholders. The bill alters the recommendation provision.

The bill specifies that members must be appointed by the Governor from nominations by the following stakeholders: the Florida Organization of Nurse Executives; Florida Hospital Association; Florida Nurses Association; Florida Health Care Association and Florida Association of Homes for the Aging; Florida Association of Colleges of Nursing; Florida Council of Nursing Education Administrators; and the President of the Senate; Speaker of the House; Commissioner of Education; and the Governor. Current board members will be replaced by a new member upon the expiration of their appointed term, unless they are reappointed.

Fiscal Impact: This bill allocates $5 of existing initial application and biennial renewal fees to the Florida Center for Nursing Trust Fund. This will reduce the contribution to the Medical Quality Assurance trust fund by approximately $795,260 annually. In addition, the Board of Nursing will have an additional estimated biennial expense of $314,950 to conduct an employment survey for the center. The bill does not provide an appropriation for this additional expense nor state where the costs of the survey will be incurred, i.e. the Board of Nursing or the Florida Center for Nursing. The Department of Health estimates that implementation of this bill will add $4.7 million to the Board of Nursing projected deficit on June 30, 2011, for a total projected deficit of $25.3 million.

This bill takes effect on July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Promote personal responsibility-The bill provides the Florida Center for Nursing the ability conduct a survey from monies received from nurse licensure fees to address nursing workforce issues in Florida.

B. EFFECT OF PROPOSED CHANGES:

The bill expands the current goals for the Florida Center for Nursing to include the development and analysis of a survey to assist in workforce planning. The survey will be conducted in partnership with the Board of Nursing as part of the application and biennial licensure renewal process. The bill expands the Center's goals to include the development of the survey. The bill does not specify the type of information that will be gathered, a date for compliance, or identify projected outcomes.

The bill specifies that the Board of Nursing will transfer $5 per license to the Florida Center for Nursing Trust Fund to assist in supporting the cost of conducting the survey and other functions of the Florida Center for Nursing. The bill stipulates that the transfer of funds will not increase licensure or licensure renewal fees. According to the Board of Nursing, the biennial cost of the survey is estimated at $314,950. The bill does not provide for this expense nor state where the costs of the survey will be incurred, i.e. the Board of Nursing or the Florida Center for Nursing.

The bill revises the composition of the governing body of the Florida Center for Nursing. Currently, all 16 members of the board of directors are appointed by the President of the Senate, the Speaker of the House, the Governor, and State Board of Education from recommendations made by key stakeholders.[1] The bill alters the recommendation provision.

The bill specifies that members must be appointed by the Governor from nominations by the following stakeholders: the Florida Organization of Nurse Executives; Florida Hospital Association; Florida Nurses Association; Florida Health Care Association and Florida Association of Homes for the Aging; Florida Association of Colleges of Nursing; Florida Council of Nursing Education Administrators; and the President of the Senate; Speaker of the House; Commissioner of Education; and the Governor. Current board members will be replaced by a new member upon the expiration of their appointed term, unless they are reappointed.

This bill takes effect on July 1, 2006.

PRESENT SITUATION

The National Center for Health Workforce Analysis at the Health Resources and Services Administration (HRSA) projects that by 2020, Florida will need 61,000 more nurses than are projected to be available. HRSA data indicates that from the year 2000 to 2020 the demand for nurses will grow 40% nationally with supply increasing only 6%.[2] The Florida Agency for Workforce Innovation has forecast 8,060 openings for registered nurses each year through 2011.[3]

Currently, there are fewer nurses entering the workforce, an increasing number leaving the profession, and an increasing demand for nurses adequately prepared to meet the needs in a changing health care environment.

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[1] See s.464.1096, F.S.

[2] Florida Center for Nursing (November 2004). *Statewide Strategic Plan for Nursing Workforce in Florida: A report from the Florida Center for Nursing.*

[3] Florida Agency for Workforce Innovation (October 2004). *Labor Market Statistics.*

The Department of Health's Division of Medical Quality Assurance

Health care practitioners in Florida are governed by professional licensing boards or councils that are independent entities that are overseen by the Department of Health's Division of Medical Quality Assurance (MQA). MQA regulates health care practitioners to ensure the health, safety and welfare of the public. Currently, MQA supports licensure and disciplinary activities for 37 professions and 6 facilities, and works with 28 boards and councils. In total, MQA regulates more than 850,000 health care practitioners and facilities. The MQA trust fund is self-sufficient and receives funding by assessing fees from health care practitioners and facilities pursuant to s.456.025(1), F.S.

The Cost of Regulating Professions and Practitioners should be Self-Sufficient

Section 456.025(1), F.S., provides that all costs of regulating health care professions and practitioners are borne solely by licensees and licensure applicants. Assessed fees should be reasonable and not serve as a barrier to licensure. Moreover, the Department of Health should operate as efficiently as possible and consider methods to streamline costs. Boards in consultation with the Department of should set renewal fees which are:

- Based on revenue projections prepared using generally accepted accounting procedures;
- Adequate to cover all expenses relating to that board identified in the department's long-range policy plan;
- Reasonable, fair, and not serve as a barrier to licensure;
- Based on potential earnings from working under the scope of the license;
- Similar to fees imposed on similar licensure types; and
- Not more than 10 percent greater than the actual cost to regulate that profession for the previous biennium.

The Board of Nursing and Licensure

As of July 2005, there were 273,304 actively licensed nurses (199,549 RNs and 62,284 LPNs). Approximately 22,400 initial licensure applications are received annually. Licensure renewals are broken into 4 groups; two groups renew each year, one in February-April and the other during May-July. It will take at least two years for the Center to receive the survey information from all licensed nurses in the state.

According to the Board of Nursing, the Florida Center for Nursing survey could be sent to new licensees at the time the initial licensure letter or when exam results are sent to applicants. However, mailing the survey at the time of licensure renewal will have to be done separately. In 2004, the department adopted a self-sealing mailer to address security concerns. This format does not allow for inclusion of other documents or surveys.

Once the Board of Nursing receives the survey information back from the applicants, the information will be entered into a computer database. The Board of Nursing is in the process of signing a data sharing agreement with the Florida Center for Nursing so they can access the information on a routine basis. The information in the database will be updated weekly.

Board of Nursing Survey and the Florida Center for Nursing Survey

Currently, the Board of Nursing conducts an annual survey of private and public nursing programs in the state. The survey gathers information on student admissions, student graduations, faculty positions, faculty qualifications, and faculty vacancies. The difference between the two surveys is that the Board of Nursing survey is sent to nursing programs and not individual licensees. Last year, the board of nursing incorporated new data elements into the existing survey to gather additional information for the Center.

Background on the Florida Center for Nursing

In March 2001, the Florida Nurses Association convened a legislative summit of nursing leaders in Tallahassee. Participants represented nurse executives, nurse educators, and nurse advocates from across the state all of whom were members of one or more of the following groups:

- Florida Nurses Association (FNA)
- Florida Hospital Association (FHA)
- Florida Organization of Nurse Executives (FONE)
- Deans and Directors of Nursing Education Programs
- Florida Board of Nursing

At the summit, the concept of a Florida Center for Nursing, which is based on North Carolina's Center for Nursing, was proposed and received unanimous support. In 2001, the Legislature established The Florida Center of Nursing. The Center was created to address issues of supply and demand for nursing, including issues of recruitment, retention, and utilization of nurse workforce resources.

Funding of the Florida Center for Nursing

The Center has been funded through annual appropriations from general revenue appropriations as well as voluntary contributions from nurses who donate monies over and above the fees imposed at the time of licensure and renewal.[4] Revenues collected are transferred from the MQA Trust Fund to the Center Trust Fund and are used to support and maintain the goals and functions of the Center.[5] The Center has received the following annual amounts from voluntary contributions:

FY 2004-2005	FY 2005-2006	FY 2006-2007
$12,363	$12,981	$13,630

According to the General Appropriations Act in FY 2004, The Center received an appropriation of $250,000 from nonrecurring general revenue. The money was provided with the stipulation that the FCN must match the appropriation with private contributions to conduct a three-year study of nurse staffing models in health care facilities. The 2004 funding was not utilized and reverted back to general revenue.

According to the General Appropriations Act in 2005, the Center was appropriated $250,000 from general revenue to contract with Palm Healthcare Foundation to conduct a three-year clinical study of nurse staffing models in health care facilities in Palm Beach County to determine the efficacy of those staffing models. The contract was contingent upon Palm Healthcare Foundation providing a match for the state funding for the second and third year of the study. The appropriation also stipulated that hospital facilities will provide in-kind support for the study. The 2005 appropriation was vetoed by the Governor.

Statutory Goals for the Florida Center for Nursing

The primary goals for the Center are:[6]

- To develop a strategic statewide plan for nursing manpower by:
  - Establishing a database on nursing supply and demand to include future projections.
- Convene various groups representative of nurses, other health care providers, business and industry, consumers, legislators, and educators to review and comment on data analysis to:
  - Review and comment on data analysis prepared for the Center;

[4] See s. 464.0195(3), F.S.
[5] Ibid.
[6] See s. 464.0195, F.S.

- Recommend systematic changes; and
- Evaluate and report findings to the Legislature.

- Enhance and promote recognition, reward, and renewal activities for nurses by:
  - Promoting programs of excellence;
  - Proposing and creating reward, recognition and renewal activities; and
  - Promoting media and image-building efforts.

The bill expands the Center's goals to include the development of a survey.

Statewide Strategic Plan on Nursing Workforce by the Florida Center for Nursing

In 2003, the FCN recognized the need for a statewide strategic plan and identified five goals to assist in the development of a plan. The following goals were identified:

- Create an ongoing statewide system to forecast the changing nurse workforce supply and demand;
- Identify systematic changes and how the allocations of new and existing resources, based on forecasting, affect the ability to meet supply and demand;
- Disseminate information of effective strategies and best practices in relation to work cultures and environments that support recruitment and retention;
- Review Florida's nursing educational system and identify approaches to improve the supply and quality of new nurses; and
- Continue to meet statutory goals as defined in s. 464.0195, F.S.

In 2005, the FCN published a report titled "Forecasting the Nursing Workforce in Florida: Development of an Implementation Plan." The plan highlights the requirements and necessary information needed to conduct a forecasting model.

Why is there a Need to Forecast?

According to the Center, there is a clear need for recurrent, dependable data to accurately forecast supply of and demand for nurses in Florida since:

- Current nurse licensure data collection is restricted to the minimum required for regulatory enforcement;
- Nurse employment data is not collected, which results in an over estimation of the actual supply of nurses (i.e., assumes that all licensed nurses are working full time in Florida); and
- Current forecasting methods utilize historical trend analysis based on existing nurse staffing, which results in an under estimation of the demand for nurses.

Board of Directors for the Florida Center for Nursing

The Center is governed by a policy-setting board of directors. The board consists of 16 members, with a simple majority of the board being nurses who represent various practice areas. Other members include representatives of other health care professions, business and industry, health care providers, and consumers. Currently, the board members must meet the following criteria:[7]

- Four members are *recommended* by the President of the Senate, at least one must be a registered nurse recommended by the Florida Organization of Nurse Executives and at least one must represent the hospital industry and is recommended by the Florida Hospital Association;

- Four members *recommended* by the Speaker of the House of Representatives, at least one must be a registered nurse recommended by the Florida Nurses Association and one must represent the long-term care industry;

[7] See s. 464.0196, F.S.

- Four members *recommended* by the Governor, two must be registered nurses;

- Four nurse educators *recommended* by the State Board of Education, one of whom must be a dean of a College of Nursing at a state university; one must be a director of a nursing program in a state community college; and

- The terms of all the members are for 3 years, and no member may serve more than two consecutive terms.

The bill alters the recommendation provision. This bill specifies that members must be appointed by the Governor from nominations from the following stakeholders:

- Florida Organization of Nurse Executives;
- Florida Hospital Association;
- Florida Nurses Association;
- Florida Health Care Association and Florida Association of Homes for the Aging;
- Florida Association of Colleges of Nursing;
- Florida Council of Nursing Education Administrators;
- President of the Senate;
- Speaker of the House;
- Commissioner of Education; and
- The Governor.

Current board members will be replaced by a new member upon the expiration of their appointed term, unless they are reappointed.

Duties of the Board of Directors

The members of board of directors have the following powers and duties:[8]

- Employ an executive director;
- Determine operational policy;
- Elect a chair and officers, to serve 2-year terms, the chair and officers may not succeed themselves;
- Establish committees of the board as needed;
- Appoint a multidisciplinary advisory council for input and advice on policy matters;
- Implement the major functions of the center as established in the goals set out in s. 464.0195, F.S.; and
- Seek and accept non-state funds for sustaining the center and carrying out center policy.

C. SECTION DIRECTORY:

Section 1. Amends s. 464.0195, F.S., to expand goals of the Florida Center for Nursing to include the development of a survey as part of a nurse's license application or renewal; provide that the Board of Nursing will transfer $5 of each initial nursing licensure and biannual renewal fee to the Florida Center for Nursing Trust Fund; and state that licensure and renewal fees may not be increased to offset the $5 transfer.
Section 2. Amends s. 464.0196, F.S., to revise the composition of the board of directors for the Florida Center for Nursing and provides term-limit criteria.
Section 3. Provides that the bill will take effect on July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

[8] Ibid.

1. Revenues:

This bill allocates $5 of existing initial application and biennial renewal fees to the Florida Center for Nursing Trust Fund. According to the Department of Health, this will reduce the contribution to the MQA trust fund by approximately $795,260 annually.

Estimated Revenue	1st Year	2nd Year (Annualized/Recurr.)
Revenue loss to the MQA Trust Fund	(795,260)	(795,260)
Total Estimated Revenue	(795,260)	(795,260)

2. Expenditures:

In addition, the Board of Nursing will have additional biennial expense of $314,950 to conduct an employment survey for the center.

Estimated Expenditures	1st Year	2nd Year (Annualized/Recurr.)
Salaries		
OPS	30,000	30,000
Expense		
Scanning and Data Management	20,000	
Duplicate and print survey	4,975	4,975
Folding /Stuffing envelopes	15,000	15,000
Postage	97,500	97,000
Operating Capital Outlay		
Total Estimated Expenditures	167,475	147,475

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Hospitals and other facilities may benefit from the workforce analysis survey on nursing conducted by the Florida Center for Nursing.

D. FISCAL COMMENTS:

The bill does not provide appropriations to cover the costs of developing and mailing the survey. It prohibits the Board of Nursing from raising fees to cover the loss of revenue resulting from the $5 per application and renewal which will go to the Center.

Prior Funding Received by the Florida Center for Nursing
In FY 2004, The Center (FCN) received an appropriation of $250,000 from nonrecurring General Revenue. The money was provided with the stipulation that the FCN must match the appropriation with private contributions to conduct a three-year study of nurse staffing models in health care facilities. The 2004 funding was not utilized and reverted back to general revenue.

In 2005, the FCN requested an appropriation of $250,000 from General Revenue to contract with Palm Healthcare Foundation to conduct a three-year clinical study of nurse staffing models in health care facilities in Palm Beach County to determine the efficacy of those staffing models. The contract was contingent upon Palm Healthcare Foundation providing a match for the state funding for the second and third year of the study. The appropriation also stipulated that hospital facilities provide in-kind support for the study. The 2005 appropriation was vetoed by the Governor.

Department of Health, Board of Nursing Projected Deficit by 2011
The Board of Nursing is not currently in a deficit but is also responsible for the costs of the Certified Nursing Assistant Registry (CNA). Taken together, Nursing and CNA are projected to be in a deficit of $1.9 million on June 30, 2007 and a projected deficit of $20.6 million on June 30, 2011. Implementation of this bill will add $4.7 million to the Board of Nursing projected deficit on June 30, 2011, for a total projected deficit of $25.3 million.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

No additional rulemaking authority is required to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Appropriation
The bill needs to provide an appropriation, or give the Board of Nursing the authority to raise licensure fees or impose an administrative fee to meet expenses.

Enactment Date
The bill takes effect July 1, 2006. According to the Board of Nursing, there would not be sufficient time to change its rules, fees, and provide the survey during the next licensure renewal. The moneys would transfer to the FNC Trust Fund through the $5 fee in May-July 2007.

The Florida Center for Nursing Business Plan
The Board of Nursing supports funding the Center through renewal fees but believes that there needs to be a business plan for the Center and its operations, along with accountability. In 4 years of existence, the FCN has held a few workshops and developed a strategic plan. The Board believes that the Center needs to play a leading role in identifying and showcasing best practices on attraction and retention of nurses and on recruiting and developing nursing faculty.

According to the Board of Nursing, the FCN has not been able to accomplish its goals. It is focused on a need for data collection for future statistical models and not on strategies which have a direct impact on the nursing shortage (i.e., nursing faculty, scholarships, elementary and middle school programs, nurse's image).

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to the Florida Center for Nursing; amending s. 464.0195, F.S.; requiring the Florida Center for Nursing and the Board of Nursing to develop a specified survey to further the center's goals; requiring the board to transfer a specified sum of each nursing licensure and licensure renewal fee to the Florida Center for Nursing Trust Fund for specified uses; providing fee limitations on the board; amending s. 464.0196, F.S.; revising membership and term-limit criteria for the center's board of directors; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (a) of subsection (2) and subsection (3) of section 464.0195, Florida Statutes, are amended to read:

464.0195 Florida Center for Nursing; goals.--

(2) The primary goals for the center shall be to:

(a) Develop a strategic statewide plan for nursing manpower in this state by:

1. Establishing and maintaining a database on nursing supply and demand in the state, to include current supply and demand, and future projections; ~~and~~

2. Selecting from the plan priorities to be addressed; and~~.~~

3. Working with the Board of Nursing to develop a survey as part of each registered nurse and licensed practical nurse application for licensure and biennial licensure renewal. Survey

data shall be submitted to the center for analysis and workforce planning.

(3)(a) The Board of Nursing shall include on its initial and renewal application forms a question asking the nurse to voluntarily contribute to funding the Florida Center for Nursing in addition to paying the fees imposed at the time of licensure and licensure renewal. Revenues collected from nurses over and above the required fees shall be transferred from the Medical Quality Assurance Trust Fund to the Florida Center for Nursing Trust Fund and shall be used solely to support and maintain the goals and functions of the center.

(b) The Board of Nursing shall transfer $5 of each nursing licensure and licensure renewal fee to the Florida Center for Nursing Trust Fund which shall be used to support, maintain, and expand the goals and functions of the center. The Board of Nursing shall not increase nursing licensure and licensure renewal fees as a result of the requirements of this paragraph.

Section 2. Subsections (1) and (2) of section 464.0196, Florida Statutes, are amended to read:

464.0196 Florida Center for Nursing; board of directors.--

(1) The Florida Center for Nursing shall be governed by a policy-setting board of directors. The board shall consist of 16 members, with a simple majority of the board being nurses representative of various practice areas. Other members shall include representatives of other health care professions, business and industry, health care providers, and consumers. The members of the board shall be appointed by the Governor as follows:

(a) One member recommended by the Florida Organization of Nurse Executives shall be a registered nurse. ~~Four members recommended by the President of the Senate, at least one of whom shall be a registered nurse recommended by the Florida Organization of Nurse Executives and at least one other representative of the hospital industry recommended by the Florida Hospital Association;~~

(b) One member recommended by the Florida Hospital Association shall be a representative of the hospital industry. ~~Four members recommended by the Speaker of the House of Representatives, at least one of whom shall be a registered nurse recommended by the Florida Nurses Association and at least one other representative of the long-term care industry;~~

(c) One member recommended by the Florida Nurses Association shall be a registered nurse. ~~Four members recommended by the Governor, two of whom shall be registered nurses; and~~

(d) One member jointly recommended by the Florida Health Care Association and the Florida Association of Homes for the Aging shall be a representative of the long-term care industry ~~Four nurse educators recommended by the State Board of Education, one of whom shall be a dean of a College of Nursing at a state university, one other shall be a director of a nursing program in a state community college~~.

(e) One member recommended by the Florida Association of Colleges of Nursing shall be a dean of a college of nursing.

(f) One member recommended by the Florida Council of Nursing Education Administrators shall be a director of a nursing program in a community college.

(g) Two members recommended by the Speaker of the House of Representatives.

(h) Two members recommended by the President of the Senate.

(i) Two members recommended by the Commissioner of Education shall be nurse educators.

(j) Four members recommended by the Governor, two of whom shall be registered nurses.

(2) Beginning July 1, 2006, each current member of the board shall be replaced with a new member upon the expiration of his or her term. The terms of all members appointed on or after July 1, 2006, shall be for 3 years, and no such member may serve more than two consecutive terms. Current members who have served only one term may be appointed for a final 3-year term. ~~The initial terms of the members shall be as follows:~~

~~(a) Of the members appointed pursuant to paragraph (1)(a), two shall be appointed for terms expiring June 30, 2005, one for a term expiring June 30, 2004, and one for a term expiring June 30, 2003.~~

~~(b) Of the members appointed pursuant to paragraph (1)(b), one shall be appointed for a term expiring June 30, 2005, two for terms expiring June 30, 2004, and one for a term expiring June 20, 2003.~~

~~(c) Of the members appointed pursuant to paragraph (1)(c), one shall be appointed for a term expiring June 30, 2005, one~~

~~for a term expiring June 30, 2004, and two for terms expiring June 30, 2003.~~

~~(d) Of the members appointed pursuant to paragraph (1)(d), the terms of two members recommended by the State Board of Education shall expire June 30, 2005; the term of the member who is a dean of a College of Nursing at a state university shall expire June 30, 2004; and the term of the member who is a director of a state community college nursing program shall expire June 30, 2003.~~

~~After the initial appointments expire, the terms of all the members shall be for 3 years, with no member serving more than two consecutive terms.~~

Section 3. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 523**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Robaina offered the following:

Amendment (with directory and title amendments)

Remove line(s) 40-45:

========== D I R E C T O R Y A M E N D M E N T ==========

Remove line(s) 15-16 and insert:

Section 1. Paragraph (a) of subsection (2) of section 464.0195, Florida Statutes, is amended to read:

========== T I T L E A M E N D M E N T ==========

Remove line(s) 5-9 and insert:

specified survey to further the center's goals; amending s. 464.0196, F.S.;

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 2 (for drafter's use only)

Bill No. **HB 523**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Robaina offered the following:

Amendment (with directory and title amendments)

Remove line(s) 23-30 and insert:

demand, and future projections. The Board of Nursing shall incorporate the collection of workforce planning data as part of each advanced registered nurse practitioner, registered nurse, and licensed practical nurse application for licensure and biennial licensure renewal. Data shall be submitted to the center for analysis and workforce planning; and

2. Selecting from the plan priorities to be addressed.

========== T I T L E A M E N D M E N T ==========

Remove line(s) 3-5 and insert:

amending s. 464.0195, F.S.; requiring the Board of Nursing to incorporate specified data as a prerequisite for certain licensure and licensure renewal; requiring

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 3 (for drafter's use only)

Bill No. **HB 523**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Robaina offered the following:

Amendment (with directory and title amendments)

Remove line(s) 93 and insert:

shall be registered nurses and one of whom must be a certified registered nurse anesthetist.

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HB523-Robaina3.doc

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 587 Health Care Practitioners
SPONSOR(S): Galvano
TIED BILLS: **IDEN./SIM. BILLS:** SB 416

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Hamrick	Mitchell
2) Business Regulation Committee			
3) Health Care Appropriations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

HB 587 provides that a practitioner must disclose the type of license under which he or she is practicing in advertisements and at the initiation of the professional relationship with a patient. The bill specifies that failing to comply is grounds for disciplinary action unless the practitioner is operating out of a facility licensed in chapters 395 and 400, F.S., which includes hospitals, ambulatory surgical centers, nursing homes, long-term care facilities, etc.

Currently, each practitioner is subject to the grounds for discipline listed in individual practice acts as well as the general provisions in ch. 456, F.S. The bill amends chapter 456 to apply uniformly to health care professions regulated by the Department of Health.

The bill stipulates that the provisions of the bill are incorporated into all statutes that make a general reference to s. 456.072, F.S. This eliminates the need to reenact specific penalty provisions in each practice act.

Fiscal Impact: This bill does not appear to have a fiscal impact on state or local governments, but may have a fiscal impact on health care providers who have to alter their advertisements, notices, and procedures. The Department of Health suggests that disciplinary investigations and prosecutions may increase.

The bill takes effect on July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Promote personal responsibility-The bill requires a physician and other health care providers such as nurses, physician assistants, mental health counselors, and optitians to disclose additional information about their credentials in advertisements and increases the enforcement responsibility of the Department of Health.

B. EFFECT OF PROPOSED CHANGES:

The bill provides that a practitioner must disclose the type of license under which he or she is practicing in advertisements and at the initiation of the professional relationship with a patient. The bill specifies that failing to comply is grounds for disciplinary action unless the practitioner is operating in a facility licensed in chapters 395 and 400, F.S., which includes hospitals, ambulatory surgical centers, nursing homes, long-term care facilities, etc.

The bill stipulates that the provisions of the bill are incorporated into all statutes that make a general reference to s. 456.072, F.S. This eliminates the need to reenact specific penalty provisions in each practice act.

PRESENT SITUATION

The findings of the bill state that health care licensure can be extremely confusing to patients. Patients can be misled into believing that the practitioner is better qualified than other health care practitioners because of misleading practice designations. Currently, each practitioner is subject to the grounds for discipline listed in individual practice acts as well as the general provisions in ch. 456, F.S. Many of the regulatory boards already have rules regarding what constitutes misleading advertising.

The bill amends chapter 456 to apply uniformly to health care professions regulated by the Department of Health. The bill states that patients need to be informed of the credentials of the health care practitioners who treat them, and that the public needs to be protected from misleading health care advertising.

The Department of Health's Division of Medical Quality Assurance

Health care practitioners in Florida are governed by professional licensing boards or councils that are independent entities that are overseen by the Department of Health's Division of Medical Quality Assurance (MQA). MQA regulates health care practitioners to ensure the health, safety and welfare of the public. Currently, MQA supports licensure and disciplinary activities for 37 professions and 6 facilities, and works with 28 boards and councils. In total, MQA regulates more than 850,000 health care practitioners and facilities.

Affected Practice Acts

The provisions of this bill will impact approximately 20 practice acts and 103 cross-references to sections 456.072, 456.072(1) and 456.072(2), F.S.

The chapters that are affected:

456	General Provisions for Health Professions	466	Dentistry, Dental Hygiene, and Dental Laboratories
457	Acupuncture	467	Midwifery
458	Medical Practice	468	Miscellaneous Professions
459	Osteopathic Medicine	478	Electrolysis
460	Chiropractic Medicine	480	Massage Practice
461	Podiatric Medicine	483	Health Testing Services
462	Naturopathy	484	Dispensing of Optical Devices and Hearing Aids
463	Optometry	486	Physical Therapy Practice
464	Nursing	490	Psychological Services
465	Pharmacy	491	Clinical, Counseling and Psychotherapy Services

Facilities Licensed in Chapters 395 and 400, Florida Statutes

The bill specifies that failing to disclose the type of license a provider is operating under is grounds for disciplinary action unless the practitioner is operating in a facility licensed in chapters 395 and 400, F.S.

Chapter 395, F.S., regulates the following entities:

- Hospitals
- Ambulatory Surgical Centers
- Trauma Centers
- Rural Hospitals
- Family Practice Teaching Hospitals

Chapter 400, F.S., regulates the following entities:

- Long-term care facilities
- Nursing homes
- Assisted living facilities
- Adult day care
- Hospices
- Intermediate care and transitional facilities for developmentally disabled persons
- Prescribed pediatric extended care facilities
- Home medical equipment providers
- Health care services pools
- Health care clinics

The bill will impact practitioners in private individual and group practices.

Prohibitions on Making Misleading Advertisements

Currently, s. 456.072(1)(a), F.S., prohibits making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession. In addition, grounds for discipline in each of the individual practice acts include a prohibition on false and misleading advertising. Many of the regulatory boards already have rules regarding what constitutes misleading advertising.

C. SECTION DIRECTORY:

Section 1. Provides findings and intent of the Legislature.
Section 2. Amends s. 456.072, F.S., to provide that a practitioner's failure to disclose the type of license under which he or she is practicing, in advertisements and at the initiation of the professional relationship with a patient, is grounds for disciplinary action, unless the practitioner is operating in a facility licensed under chapters 395 or 400, F.S.
Section 3. Provides that the bill will take effect on July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   See D. Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care providers may have to change their advertisements, notices, and office procedures to comply with the provisions of this bill.

D. FISCAL COMMENTS:

According to the Department of Health, an increase in the number of complaints of health care providers failing to fully disclose licensure information would increase the amount of disciplinary investigations and prosecutions.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Additional rulemaking authority will be needed to allow the Department of Health to promulgate rules outlining how a licensee will disclose the type of license under which he or she is practicing.

DRAFTING ISSUES OR OTHER COMMENTS:

An amendment needs to be drafted to provide the Department of Health with additional rule-making authority.

According to the Department of Heath, the bill will help make clear to patients whether the person providing care is a physician, a physician assistant, an advanced registered nurse practitioner, other licensed professional, or an unlicensed assistant.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to health care practitioners; providing legislative findings and intent; amending s. 456.072, F.S., relating to grounds for discipline, penalties, and enforcement applicable to health care practitioners; providing that a practitioner's failure to provide the type of license under which he or she is operating in health care advertisements and in professional relationships with patients constitutes grounds for disciplinary action; providing exceptions; providing penalties; specifying that a reference to the section constitutes a general reference under the doctrine of incorporation by reference; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. The Legislature finds that there exists a compelling state interest in patients being informed of the credentials of the health care practitioners who treat them and in the public being protected from misleading health care advertising. The Legislature further finds that the areas of licensure for the practice of health care can be extremely confusing for patients and that health care practitioners can easily mislead patients into believing that the practitioner is better qualified than other health care practitioners simply by creating a sham practice designation. Therefore, the Legislature has determined that the most direct and effective manner in which to protect patients from this identifiable harm is to

ensure that patients and the public be informed of the training of health care practitioners and intends by this act to require the provision of the information.

Section 2. Section 456.072, Florida Statutes, is amended to read:

456.072 Grounds for discipline; penalties; enforcement.--

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

(a) Making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession.

(b) Intentionally violating any rule adopted by the board or the department, as appropriate.

(c) Being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.

(d) Using a Class III or a Class IV laser device or product, as defined by federal regulations, without having complied with the rules adopted under ~~pursuant to~~ s. 501.122(2) governing the registration of the ~~such~~ devices.

(e) Failing to comply with the educational course requirements for human immunodeficiency virus and acquired immune deficiency syndrome.

(f) Having a license or the authority to practice any regulated profession revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing

authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law. The licensing authority's acceptance of a relinquishment of licensure, stipulation, consent order, or other settlement, offered in response to or in anticipation of the filing of charges against the license, shall be construed as action against the license.

(g) Having been found liable in a civil proceeding for knowingly filing a false report or complaint with the department against another licensee.

(h) Attempting to obtain, obtaining, or renewing a license to practice a profession by bribery, by fraudulent misrepresentation, or through an error of the department or the board.

(i) Except as provided in s. 465.016, failing to report to the department any person who the licensee knows is in violation of this chapter, the chapter regulating the alleged violator, or the rules of the department or the board.

(j) Aiding, assisting, procuring, employing, or advising any unlicensed person or entity to practice a profession contrary to this chapter, the chapter regulating the profession, or the rules of the department or the board.

(k) Failing to perform any statutory or legal obligation placed upon a licensee. For purposes of this section, failing to repay a student loan issued or guaranteed by the state or the Federal Government in accordance with the terms of the loan or failing to comply with service scholarship obligations shall be considered a failure to perform a statutory or legal obligation,

and the minimum disciplinary action imposed shall be a suspension of the license until new payment terms are agreed upon or the scholarship obligation is resumed, followed by probation for the duration of the student loan or remaining scholarship obligation period, and a fine equal to 10 percent of the defaulted loan amount. Fines collected shall be deposited into the Medical Quality Assurance Trust Fund.

(l) Making or filing a report which the licensee knows to be false, intentionally or negligently failing to file a report or record required by state or federal law, or willfully impeding or obstructing another person to do so. Such reports or records shall include only those that are signed in the capacity of a licensee.

(m) Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or scheme in or related to the practice of a profession.

(n) Exercising influence on the patient or client for the purpose of financial gain of the licensee or a third party.

(o) Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities the licensee knows, or has reason to know, the licensee is not competent to perform.

(p) Delegating or contracting for the performance of professional responsibilities by a person when the licensee delegating or contracting for performance of <u>the</u> ~~such~~ responsibilities knows, or has reason to know, <u>the</u> ~~such~~ person is not qualified by training, experience, and authorization when

required to perform them.

(q) Violating a lawful order of the department or the board, or failing to comply with a lawfully issued subpoena of the department.

(r) Improperly interfering with an investigation or inspection authorized by statute, or with any disciplinary proceeding.

(s) Failing to comply with the educational course requirements for domestic violence.

(t) In any advertisement for health care services, and no later than at the time of the initiation of the professional relationship with a patient, failing to provide the type of license under which the practitioner is operating. This paragraph does not apply to a practitioner while the practitioner is providing services in a facility licensed under chapter 395 or chapter 400.

(u) ~~(t)~~ Failing to comply with the requirements of ss. 381.026 and 381.0261 to provide patients with information about their patient rights and how to file a patient complaint.

(v) ~~(u)~~ Engaging or attempting to engage in sexual misconduct as defined and prohibited in s. 456.063(1).

(w) ~~(v)~~ Failing to comply with the requirements for profiling and credentialing, including, but not limited to, failing to provide initial information, failing to timely provide updated information, or making misleading, untrue, deceptive, or fraudulent representations on a profile, credentialing, or initial or renewal licensure application.

(x) ~~(w)~~ Failing to report to the board, or the department

if there is no board, in writing within 30 days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction. Convictions, findings, adjudications, and pleas entered into prior to the enactment of this paragraph must be reported in writing to the board, or department if there is no board, on or before October 1, 1999.

(y) ~~(x)~~ Using information about people involved in motor vehicle accidents which has been derived from accident reports made by law enforcement officers or persons involved in accidents under ~~pursuant to~~ s. 316.066, or using information published in a newspaper or other news publication or through a radio or television broadcast that has used information gained from such reports, for the purposes of commercial or any other solicitation whatsoever of the people involved in the ~~such~~ accidents.

(z) ~~(y)~~ Being unable to practice with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition. In enforcing this paragraph, the department shall have, upon a finding of the secretary or the secretary's designee that probable cause exists to believe that the licensee is unable to practice because of the reasons stated in this paragraph, the authority to issue an order to compel a licensee to submit to a mental or physical examination by physicians designated by the department. If the licensee refuses to comply with the ~~such~~ order, the department's order directing the ~~such~~ examination may be enforced by filing a

petition for enforcement in the circuit court where the licensee resides or does business. The department shall be entitled to the summary procedure provided in s. 51.011. A licensee or certificateholder affected under this paragraph shall at reasonable intervals be afforded an opportunity to demonstrate that he or she can resume the competent practice of his or her profession with reasonable skill and safety to patients.

(aa) ~~(z)~~ Testing positive for any drug, as defined in s. 112.0455, on any confirmed preemployment or employer-ordered drug screening when the practitioner does not have a lawful prescription and legitimate medical reason for using the ~~such~~ drug.

(bb) ~~(aa)~~ Performing or attempting to perform health care services on the wrong patient, a wrong-site procedure, a wrong procedure, or an unauthorized procedure or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition. For the purposes of this paragraph, performing or attempting to perform health care services includes the preparation of the patient.

(cc) ~~(bb)~~ Leaving a foreign body in a patient, such as a sponge, clamp, forceps, surgical needle, or other paraphernalia commonly used in surgical, examination, or other diagnostic procedures. For the purposes of this paragraph, it shall be legally presumed that retention of a foreign body is not in the best interest of the patient and is not within the standard of care of the profession, regardless of the intent of the professional.

(dd) ~~(cc)~~ Violating any provision of this chapter, the

applicable practice act, or any rules adopted pursuant thereto.

(ee) ~~(dd)~~ With respect to making a personal injury protection claim as required by s. 627.736, intentionally submitting a claim, statement, or bill that has been "upcoded" as defined in s. 627.732.

(ff) ~~(ee)~~ With respect to making a personal injury protection claim as required by s. 627.736, intentionally submitting a claim, statement, or bill for payment of services that were not rendered.

(gg) ~~(ff)~~ Engaging in a pattern of practice when prescribing medicinal drugs or controlled substances which demonstrates a lack of reasonable skill or safety to patients, a violation of any provision of this chapter, a violation of the applicable practice act, or a violation of any rules adopted under ~~pursuant to~~ this chapter or the applicable practice act of the prescribing practitioner. Notwithstanding s. 456.073(13), the department may initiate an investigation and establish such a pattern from billing records, data, or any other information obtained by the department.

(hh) ~~(gg)~~ Being terminated from a treatment program for impaired practitioners, which is overseen by an impaired practitioner consultant as described in s. 456.076, for failure to comply, without good cause, with the terms of the monitoring or treatment contract entered into by the licensee, or for not successfully completing any drug treatment or alcohol treatment program.

(2) When the board, or the department when there is no board, finds any person guilty of the grounds set forth in

subsection (1) or of any grounds set forth in the applicable practice act, including conduct constituting a substantial violation of subsection (1) or a violation of the applicable practice act which occurred prior to obtaining a license, it may enter an order imposing one or more of the following penalties:

(a) Refusal to certify, or to certify with restrictions, an application for a license.

(b) Suspension or permanent revocation of a license.

(c) Restriction of practice or license, including, but not limited to, restricting the licensee from practicing in certain settings, restricting the licensee to work only under designated conditions or in certain settings, restricting the licensee from performing or providing designated clinical and administrative services, restricting the licensee from practicing more than a designated number of hours, or any other restriction found to be necessary for the protection of the public health, safety, and welfare.

(d) Imposition of an administrative fine not to exceed $10,000 for each count or separate offense. If the violation is for fraud or making a false or fraudulent representation, the board, or the department if there is no board, must impose a fine of $10,000 per count or offense.

(e) Issuance of a reprimand or letter of concern.

(f) Placement of the licensee on probation for a period of time and subject to such conditions as the board, or the department when there is no board, may specify. Those conditions may include, but are not limited to, requiring the licensee to undergo treatment, attend continuing education courses, submit

to be reexamined, work under the supervision of another licensee, or satisfy any terms which are reasonably tailored to the violations found.

(g) Corrective action.

(h) Imposition of an administrative fine in accordance with s. 381.0261 for violations regarding patient rights.

(i) Refund of fees billed and collected from the patient or a third party on behalf of the patient.

(j) Requirement that the practitioner undergo remedial education.

In determining what action is appropriate, the board, or department when there is no board, must first consider what sanctions are necessary to protect the public or to compensate the patient. Only after those sanctions have been imposed may the disciplining authority consider and include in the order requirements designed to rehabilitate the practitioner. All costs associated with compliance with orders issued under this subsection are the obligation of the practitioner.

(3)(a) Notwithstanding subsection (2), if the ground for disciplinary action is the first-time failure of the licensee to satisfy continuing education requirements established by the board, or by the department if there is no board, the board or department, as applicable, shall issue a citation in accordance with s. 456.077 and assess a fine, as determined by the board or department by rule. In addition, for each hour of continuing education not completed or completed late, the board or department, as applicable, may require the licensee to take 1

additional hour of continuing education for each hour not completed or completed late.

(b) Notwithstanding subsection (2), if the ground for disciplinary action is the first-time violation of a practice act for unprofessional conduct, as used in ss. 464.018(1)(h), 467.203(1)(f), 468.365(1)(f), and 478.52(1)(f), and no actual harm to the patient occurred, the board or department, as applicable, shall issue a citation in accordance with s. 456.077 and assess a penalty as determined by rule of the board or department.

(4) In addition to any other discipline imposed through final order, or citation, entered on or after July 1, 2001, under ~~pursuant to~~ this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is no board, shall assess costs related to the investigation and prosecution of the case. The ~~Such~~ costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there in no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto. In any case where the board or the department imposes a fine or assessment and the fine or assessment is not paid within a reasonable time, the ~~such~~ reasonable time to be prescribed in the rules of the board, or

the department when there is no board, or in the order assessing the ~~such~~ fines or costs, the department or the Department of Legal Affairs may contract for the collection of, or bring a civil action to recover, the fine or assessment.

(5) In addition to, or in lieu of, any other remedy or criminal prosecution, the department may file a proceeding in the name of the state seeking issuance of an injunction or a writ of mandamus against any person who violates any of the provisions of this chapter, or any provision of law with respect to professions regulated by the department, or any board therein, or the rules adopted pursuant thereto.

(6) If ~~In the event~~ the board, or the department when there is no board, determines that revocation of a license is the appropriate penalty, the revocation shall be permanent. However, the board may establish by rule requirements for reapplication by applicants whose licenses have been permanently revoked. The ~~Such~~ requirements may include, but are ~~shall~~ not ~~be~~ limited to, satisfying current requirements for an initial license.

(7) The purpose of this section is to facilitate uniform discipline for those actions made punishable under this section and, to this end, a reference to this section constitutes a general reference under the doctrine of incorporation by reference.

Section 3. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 587**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Galvano offered the following:

Amendment (with directory and title amendments)

Remove line(s) 122-128 and insert:

(t) Failing to identify through written notice, which may include the wearing of a name tag, or orally to a patient the type of license under which the practitioner is practicing. Any advertisement for health care services must identify the type of license the practitioner holds. This paragraph does not apply to a practitioner while the practitioner is providing services in a facility licensed under chapter 395 or chapter 400. Each board or the department where there is no board is authorized by rule to determine how its practitioners may comply with this disclosure requirement.

========== T I T L E A M E N D M E N T ==========

Remove line(s) 6-10 and insert:

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providing that a practitioner's failure to identify the type of license under which he or she is practicing constitutes grounds for disciplinary action; providing exceptions; authorizing certain entities to determine compliance with a disclosure requirement; providing

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 685 Veterinary Drug Distribution
SPONSOR(S): Coley and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1540

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell	Mitchell
2) Agriculture Committee			
3) Health Care Appropriations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

HB 685 establishes a new type of prescription drug wholesaler permit, the "limited prescription drug veterinary wholesaler permit." The limited prescription drug wholesaler permit is created for any person who engages in the distribution, in or into the state to veterinarians, of veterinarian prescription drugs and prescription drugs regulated by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.[1] The bill provides several permit requirements, including a $20,000 bond or equivalent surety requirement, and provides parameters for permit holders.

The bill defines any human prescription drug, regulated under s. 503(b), as an adulterated drug if it has been returned by a veterinarian to a limited prescription drug veterinary wholesaler.

The bill provides that no more than 30 percent of drug sales by limited prescription drug veterinary wholesalers may be prescription drugs prescribed for human use. It also requires a limited prescription drug veterinary wholesaler to comply with pedigree paper tracking requirements under s. 499.0121, F.S., except that the permit holder is not required to comply with the pedigree paper requirements of s. 499.0121(6)(f), F.S., when a prescription drug is distributed wholesale to a veterinarian.

The bill provides a fee for a limited prescription drug veterinary wholesaler's permit of not less than $300 or no more than $500 annually.

The bill requires the Department of Health (DOH) to inspect each limited prescription drug wholesaler. It authorizes DOH to order immediate closures of a limited prescription drug veterinary wholesaler if DOH determines that it presents an immediate danger to the public health safety and welfare.

The Department of Health estimates that, with the creation of the limited veterinary wholesaler permit, there will be a yearly loss of $3,000 that will have no effect on current operations.

The effective date of the bill is July 1, 2006.

[1] Section 503(b) of the Federal Food, Drug, and Cosmetic Act regulates pharmaceutical drug intended for human consumption.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – HB 685 creates a new prescription drug wholesaler permit, the limited prescription drug veterinary wholesaler permit. The new permit would allow veterinary wholesalers to provide legend drugs intended for human use but limits the sales to no more than 30 percent. The bill decreases requirements for veterinary wholesalers that wish to provide legend drugs intended for human use. The Department of Health estimates a yearly loss of $3,000 of regulatory fees with the creation of the limited veterinary wholesaler permit.

B. EFFECT OF PROPOSED CHANGES:

HB 685 establishes a new type of prescription drug wholesaler permit, the "limited prescription drug veterinary wholesaler permit." The limited prescription drug wholesaler permit is created for any person who engages in the distribution, in or into the state, of veterinarian prescription drugs and prescription drugs subject to, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act[2] to veterinarians. The bill provides several permit requirements, including a $20,000 bond or equivalent surety requirement, and provides parameters for permit holders.

The bill defines any prescription drug subject to, defined by, or described by s. 503(b), which has been returned by a veterinarian to a limited prescription drug veterinary wholesaler as an adulterated drug.

The bill specifies that no more than 30 percent of drug sales[3] by limited prescription drug veterinary wholesalers may be prescription drugs prescribed for human use. It also requires a limited prescription drug veterinary wholesaler to comply with pedigree paper tracking requirements under s. 499.0121, F.S., except that the permit holder is not required to comply with the pedigree paper requirements of s. 499.0121(6)(f), F.S., upon the wholesale distribution of a prescription drug to a veterinarian.

The bill permits intracompany sale or transfer of prescription drugs from an out of state establishment, that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence, to a licensed limited prescription drug veterinarian wholesaler. Both wholesalers must operate under the same name, and comply with the recordkeeping requirements of s. 499.0121(6), F.S.

The bill provides a fee for a limited prescription drug veterinary wholesaler's permit of not less than $300 or no more than $500 annually. It also requires the Department of Health (DOH) to inspect each limited prescription drug wholesaler. It authorizes DOH to order immediate closures of a limited prescription drug veterinary wholesaler if DOH determines that it presents an immediate danger to the public health safety and welfare.

Limited Veterinarian Prescription Drug Wholesaler Permit Requirements

The bill provides the following permit requirements and conditions under the permit:

- The permit holder must be engaged in the business of wholesaling prescription and veterinary legend drugs on a full-time basis;
- No more than 30 percent of drug sales may be prescription drugs prescribed for human use;

[2] Section 503(b) of the Federal Food, Drug, and Cosmetic Act regulates pharmaceutical drug intended for human consumption.

[3] According to a survey conducted by the American Veterinary Distributors Association (AVDA) human drug sales compromise no more than (30%) of the annual sales volume of veterinary wholesalers who sell all types of veterinary products to veterinarians.

- The permit holder may not be licensed in any state to wholesale prescription drugs subject to s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans;
- The permit holder must submit a $20,000 bond or equivalent surety;
- The permit holder must maintain a license or permit to engage in wholesale distribution of prescription drugs at all times in compliance with the laws of the state in which it is a resident;
- The permit holder must comply with s. 499.0121, F.S., except that the permit holder is not required to comply with the pedigree paper requirements of s. 499.0121(6)(f), F.S., for wholesale distribution of a prescription drug to a veterinarian; and
- The permit holder may not return to inventory for subsequent wholesale distribution any drug federally regulated under s. 503(b) which has been returned by a veterinarian.

The effective date of the bill is July 1, 2006.

PRESENT SITUATION

Overview

The Bureau of Statewide Pharmacy Services of DOH is responsible for regulating the wholesale distribution of drugs intended for human consumption[4] and veterinary legend drugs[5] in Florida under the Florida Drug and Cosmetic Act. The Florida Drug and Cosmetic Act is codified in ch. 499, F.S.

Under s. 499.012, F.S., "wholesale distributor" is defined to mean any person engaged in wholesale distribution of prescription drugs. Persons or entities which distribute wholesale veterinary prescription drugs must obtain a permit under the Florida Drug and Cosmetic Act.

Currently, wholesalers that distribute drugs to veterinarians must have a prescription drug wholesaler's permit, an out-of-state wholesaler's permit, a retail pharmacy wholesaler's permit, or a veterinary prescription drug wholesaler permit. However, most often wholesalers that distribute drugs to veterinarians register as a prescription drug wholesaler or a veterinarian prescription drug wholesaler.

Veterinarian prescription drug wholesalers are limited to only distributing prescription drugs developed and intended for animal use. According to an industry representative, some prescription drugs intended for human use do not have an equivalent prescription drug intended for animal use. Because of this deficiency, veterinarians may prescribe human drugs to animals. According to the Department of Health human medications sold by veterinarians are not on any list of adulterated, counterfeit, or diverted drugs. The human drugs sold by veterinarians include eye ointment, antibiotics, allergy medications, and topical anesthetics.

Existing Regulations

Veterinary Prescription Drug Wholesaler Permits

Section 499.01, F.S., requires a permit for any person or establishment that wishes to operate as a veterinary prescription drug wholesaler. Veterinary prescription drug wholesaler is defined as any person engaged in the wholesale distribution of veterinary prescription drugs in or into Florida.[6]

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[4] Defined in s. 499.003(25) as "legend drug," "prescription drug," or "medicinal drug" to mean any drug, including, but not limited to, finished dosage forms, or active ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

[5] Defined in s. 499.0122(1)(c), F.S., to mean a legend drug intended only for veterinary use. The label the veterinary legend drug must bear this statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

[6] Section 499.003(40), Florida Statutes.

Prescription Drug Wholesalers

All prescription drug wholesalers are required to post a $100,000 bond and to file an extensive permit application that includes the submission of fingerprint cards for all key individuals associated with the wholesaler's operations in order for a criminal history check to be performed. In addition, each prescription drug wholesaler must have a designated representative who has successfully passed an examination on federal and state laws, and department rules, relating to the wholesale distribution of prescription drugs.

	Prescription Drug Wholesaler	Limited Veterinarian Prescription Drug Wholesaler (proposed permit)	Veterinarian Prescription Drug Wholesaler
Type of Prescription Drugs Dispensed	Legend drugs defined or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.	May dispense up to 30% of sales from legend drugs.	Veterinarian legend drugs only.
Required Deposit	$100,000 bond, certificate of deposit, or letter of credit	$20,000 bond, certificate of deposit, or letter of credit	None required.
Authorized yearly fees	$800 Annually s. 499.041(2)(a), F.S.	$300-$500 Annually (proposed legislation)	$500 s. 499.041(g), F.S.

Pedigree Papers

Pedigree papers are the key standard for control of the wholesale drug industry designed to prevent drug diversion, fraud, and counterfeiting. They require wholesalers to provide purchasers with a written sales history tracing each drug back to its initial manufacturer. These written histories, commonly referred to as pedigree papers, provide an audit trail and should contain specific information about each sales transaction, such as the name and address of each previous purchaser of the drug.

Currently, beginning July 1, 2006 prescription drug wholesalers will be required to pass pedigree papers down to the retail levels. Wholesalers who pass pedigree papers to veterinarians are included in this provision.

BACKGROUND

Florida Drug & Cosmetic Act

Pursuant to the Florida Drug and Cosmetic Act, part I, chapter 499, Florida Statutes, the Department of Health (DOH) is responsible for administering and enforcing efforts to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices and cosmetics. Wholesalers, manufacturers and distributors of drugs or devices must be permitted by the department or otherwise be exempt.[7]

Under the Florida Drug and Cosmetic Act (or the Act), any person who is at least 18 years of age or older and who pays the permit fee, and submits specified information, may with certain exceptions, obtain a permit as a prescription drug wholesaler.[8] The applicant must not have been found guilty of a

[7] Drug marketing is also subject to regulation under the Federal Prescription Drug Marketing Act of 1987 which establishes minimum standards for the prescription drug industry that include requirements for an audit trail of sales transactions.

[8] See ss. 499.01 and 499.012, F.S. The permitting requirements for a number of establishments licensed or permitted by the Department of Health to engage in activities regulated under the Florida Drug and Cosmetic Act are the same. Such establishments include: prescription drug manufacturer; over-the-counter drug manufacturer; compressed medical gas manufacturer; device manufacturer; cosmetic manufacturer; prescription drug wholesaler; compressed medical gas wholesaler; out-of state prescription drug wholesaler; retail pharmacy drug wholesaler; veterinary legend drug retail establishment; medical oxygen retail establishment; complimentary drug distributor; or restricted prescription drug distributor.

violation of a law that directly relates to a drug, device, or cosmetic, regardless of adjudication. The applicant must submit information on contact persons for each facility used by the applicant for the storage, handling and distribution of prescription drugs. The permit, once granted, may be renewed biennially.

An out-of-state prescription drug wholesaler distributor located outside of Florida must be permitted by the Department of Health (DOH). The department is authorized to adopt rules that allow out-of-state drug wholesalers to obtain a drug wholesale permit on the basis of reciprocity in Florida to the extent that an out-of-state drug wholesaler possesses a valid permit from another state that has requirements that are comparable to those of Florida and can show that the other state from which the wholesaler holds a permit would extend reciprocal treatment under its laws to a Florida-permitted drug wholesaler. According to DOH, there are approximately 450 prescription drug wholesalers located in Florida and 900[9] out-of-state wholesalers, of which less than 10 percent are one of the three large full-line wholesalers or their distribution centers, or major full-line regional wholesalers. The remainder are secondary wholesalers that primarily buy and sell among other prescription drug wholesalers rather than to end-users such as hospitals or other health care entities, including physicians or pharmacies.

The Act requires prescription drug wholesalers to maintain records that provide a complete audit trail of prescription drugs from purchase to sale or other disposition. Such records known as "pedigree papers" must include a written statement of all previous sales of the drug that is sold in a wholesale market.

The Florida Drug and Cosmetic Act, specifies criminal penalties for violations relating to activities regulated by the department under the Act. Such criminal offenses are, with few exceptions, punishable as a second-degree misdemeanor (a maximum fine of $1,000 or 1 year imprisonment) if it is a second conviction for the violation of the Act.

C. SECTION DIRECTORY:

Section 1. – Amends s. 499.006, F.S., to define a prescription drug returned by a veterinarian to a limited prescription drug veterinary wholesaler as an adulterated drug. Prescription drugs are those regulated by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

Section 2. – Amends s. 499.01, F.S., to require a permit for any person or establishment that intends to operate as a limited prescription drug veterinary wholesaler. The bill provides that the limited drug veterinary wholesaler permit may not be issued to the address of a health care entity or pharmacy licensed under ch. 465, F.S., except as provided in s. 499.01(2)(d), F.S.

Section 3. – Amends s. 499.012, F.S., to establish a limited prescription drug veterinary wholesaler permit. The bill provides several permit requirements and conditions under the permit, including a $20,000 bond or equivalent surety requirement, and provides permissible transactions under the permit.

Section 4. – Amends s. 499.01221(1)(d) F.S., to delete veterinarians from the group of persons or entities to whom a veterinary legend drug retail establishment may sell veterinary legend drugs. The bill would permit a veterinary legend drug retail establishment to only sell veterinary legend drugs to the public.

Section 5. – Amends s. 499.041, F.S., to require a fee for a limited prescription drug veterinary wholesaler's permit. The bill provides the fee may not be less than $300 or no more than $500 annually.

Section 6. – Amends s. 499.065, F.S., to require the Department of Health (DOH) to inspect each limited prescription drug veterinary wholesaler. The bill permits DOH to order the immediate closure of limited prescription drug veterinary wholesaler if DOH determines that it presents an immediate danger to the public health, safety, or welfare.

[9] According to the Department of Health 2003 records.

Section 7. – Provides an effective date of July 1, 2005.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Estimated Revenue	1st Year	2nd Year (Annualized/Recurr.)
Decrease in permit fee revenue $300 for est. 10 permits	-3,000	-3,000
Total Estimated Revenue	- $3,000	- $3,000

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Under the proposed legislation veterinary wholesalers, who wish to offer some legend drugs intended for human use, would have the options of obtaining a limited veterinary prescription drug wholesaler permit instead of a prescription drug wholesaler permit. Because the limited veterinary prescription drug wholesaler has fewer requirements than the prescription drug wholesaler permit, some cost savings may be realized. Wholesalers who choose to obtain the newly created permit may pass on their savings to their customers.

D. FISCAL COMMENTS:

The Department of Health (DOH) estimates that no more that 10 establishments would apply and qualify to become a limited veterinarian wholesaler. As a result, the impact, assuming each is currently permitted as a prescription drug wholesaler or out-of-state prescription drug wholesaler, would be a decrease in revenue of $3,000 annually. According to DOH the $3,000 loss in revenue will have no effect on operations.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Health has the necessary rulemaking authority to carry out the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to veterinary drug distribution; amending s. 499.006, F.S.; providing that a drug is adulterated if it is a certain prescription drug that has been returned by a veterinarian to a limited prescription drug veterinary wholesaler; amending s. 499.01, F.S.; requiring a limited prescription drug veterinary wholesaler to obtain a permit for operation from the Department of Health; providing that a permit for a limited prescription drug veterinary wholesaler may not be issued to the address of certain health care entities; amending s. 499.012, F.S.; revising permit requirements for a veterinary prescription drug wholesaler that distributes prescription drugs; establishing a permit for a limited prescription drug veterinary wholesaler; providing requirements; providing an exception; amending s. 499.0122, F.S.; redefining the term "veterinary legend drug retail establishment"; amending s. 499.041, F.S.; requiring the department to assess an annual fee within a certain monetary range for a limited prescription drug veterinary wholesaler permit; amending s. 499.065, F.S.; requiring the department to inspect each limited prescription drug veterinary wholesaler establishment; authorizing the department to determine that a limited prescription drug veterinary wholesaler establishment is an imminent danger to the public; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 499.006, Florida Statutes, is amended to read:

499.006 Adulterated drug or device.--A drug or device is adulterated:

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance;

(2) If it has been produced, prepared, packed, or held under conditions whereby it could have been contaminated with filth or rendered injurious to health;

(3) If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practices to assure that the drug meets the requirements of ss. 499.001-499.081 and that the drug has the identity and strength, and meets the standard of quality and purity, which it purports or is represented to possess;

(4) If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which could render the contents injurious to health;

(5) If it is a drug and it bears or contains, for the purpose of coloring only, a color additive that is unsafe within the meaning of the federal act; or, if it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, and it is unsafe within the meaning of the federal act;

(6) If it purports to be, or is represented as, a drug the name of which is recognized in the official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. The determination as to strength, quality, or purity must be made in accordance with the tests or methods of assay set forth in such compendium, or, when such tests or methods of assay are absent or inadequate, in accordance with those tests or methods of assay prescribed under authority of the federal act. A drug defined in the official compendium is not adulterated under this subsection merely because it differs from the standard of strength, quality, or purity set forth for that drug in such compendium if its difference in strength, quality, or purity from such standard is plainly stated on its label;

(7) If it is not subject to subsection (6) and its strength differs from, or its purity or quality falls below the standard of, that which it purports or is represented to possess;

(8) If it is a drug:

(a) With which any substance has been mixed or packed so as to reduce the quality or strength of the drug; or

(b) For which any substance has been substituted wholly or in part;

(9) If it is a drug or device for which the expiration date has passed; ~~or~~

(10) If it is a legend drug for which the required pedigree paper is nonexistent, fraudulent, or incomplete under the requirements of ss. 499.001-499.081 or applicable rules, or

that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so; or.

(11) If it is a prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian to a limited prescription drug veterinary wholesaler.

Section 2. Subsection (1) and paragraph (d) of subsection (2) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits; applications; renewal; general requirements.--

(1) Prior to operating, a permit is required for each person and establishment that intends to operate as:

(a) A prescription drug manufacturer;

(b) A prescription drug repackager;

(c) An over-the-counter drug manufacturer;

(d) A compressed medical gas manufacturer;

(e) A device manufacturer;

(f) A cosmetic manufacturer;

(g) A prescription drug wholesaler;

(h) A veterinary prescription drug wholesaler;

(i) A compressed medical gas wholesaler;

(j) An out-of-state prescription drug wholesaler;

(k) A nonresident prescription drug manufacturer;

(l) A freight forwarder;

(m) A retail pharmacy drug wholesaler;

(n) A veterinary legend drug retail establishment;

(o) A medical oxygen retail establishment;

(p) A complimentary drug distributor; ~~or~~

(q) A restricted prescription drug distributor; or~~.~~

(r) A limited prescription drug veterinary wholesaler.

(2)

(d) A permit for a prescription drug manufacturer, prescription drug repackager, prescription drug wholesaler, limited prescription drug veterinary wholesaler, or retail pharmacy wholesaler may not be issued to the address of a health care entity or to a pharmacy licensed under chapter 465, except as provided in this paragraph. The department may issue a prescription drug manufacturer permit to an applicant at the same address as a licensed nuclear pharmacy, which is a health care entity, for the purpose of manufacturing prescription drugs used in positron emission tomography or other radiopharmaceuticals, as listed in a rule adopted by the department pursuant to this paragraph. The purpose of this exemption is to assure availability of state-of-the-art pharmaceuticals that would pose a significant danger to the public health if manufactured at a separate establishment address from the nuclear pharmacy from which the prescription drugs are dispensed. The department may also issue a retail pharmacy wholesaler permit to the address of a community pharmacy licensed under chapter 465 which does not meet the definition of a closed pharmacy in s. 499.003.

Section 3. Paragraph (g) of subsection (2) of section 499.012, Florida Statutes, is amended, and paragraph (h) is added to that subsection, to read:

499.012 Wholesale distribution; definitions; permits;

applications; general requirements.--

(2) The following types of wholesaler permits are established:

(g) A veterinary prescription drug wholesaler permit.--A veterinary prescription drug wholesaler permit is required for any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesaler that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesaler, an ~~or~~ out-of-state prescription drug wholesaler, or a limited prescription drug veterinary wholesaler in lieu of the veterinary prescription drug wholesaler permit. A veterinary prescription drug wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except those set forth in s. 499.0121(6)(d), (e), or (f).

(h) Limited prescription drug veterinary wholesaler permit.--Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesaler, or out-of-state prescription drug wholesaler, a limited prescription drug veterinary wholesaler permit is required for any person that engages in the distribution in or into this state of veterinary prescription drugs and prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to veterinarians under the following conditions:

1. The person is engaged in the business of wholesaling

prescription and veterinary legend drugs to veterinarians on a full-time basis.

2. No more than 30 percent of prescription drug sales may be prescription drugs approved for human use which are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

3. The person is not permitted, licensed, or otherwise authorized in any state to wholesale prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.

4. A limited prescription drug veterinary wholesaler that applies to the department for a new permit or the renewal of a permit must submit a bond of $20,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in ss. 499.001-499.081 which involves the permittee is concluded, including any appeal, whichever occurs later.

5. A limited prescription drug veterinary wholesaler must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

6. A limited prescription drug veterinary wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except that a limited prescription drug veterinary wholesaler is not required to provide a pedigree paper as required by s. 499.0121(6)(f) upon the wholesale distribution of a prescription drug to a veterinarian.

7. A limited prescription drug veterinary wholesaler may not return to inventory for subsequent wholesale distribution any prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian.

8. An out-of-state prescription drug wholesaler's permit or a limited prescription drug veterinary wholesaler permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence to a licensed limited prescription drug veterinary wholesaler in this state if both wholesalers conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. 499.0121(6) must be followed for this transaction.

Section 4. Paragraph (d) of subsection (1) of section 499.0122, Florida Statutes, is amended to read:

499.0122 Medical oxygen and veterinary legend drug retail establishments; definitions, permits, general requirements.--

(1) As used in this section, the term:

(d) "Veterinary legend drug retail establishment" means a person permitted to sell veterinary legend drugs to the public ~~or to veterinarians,~~ but does not include a pharmacy licensed under chapter 465.

1. The sale to the public must be based on a valid written order from a veterinarian licensed in this state who has a valid client-veterinarian relationship with the purchaser's animal.

2. Veterinary legend drugs may not be sold in excess of the amount clearly indicated on the order or beyond the date indicated on the order.

3. An order may not be valid for more than 1 year.

4. A veterinary legend drug retail establishment may not purchase, sell, trade, or possess human prescription drugs or any controlled substance as defined in chapter 893.

5. A veterinary legend drug retail establishment must sell a veterinary legend drug in the original, sealed manufacturer's container with all labeling intact and legible. The department may adopt by rule additional labeling requirements for the sale of a veterinary legend drug.

Section 5. Paragraph (h) is added to subsection (2) of section 499.041, Florida Statutes, to read:

499.041 Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.--

(2) The department shall assess an applicant that is

required to have a wholesaling permit an annual fee within the ranges established in this section for the specific type of wholesaling.

(h) The fee for a limited prescription drug veterinary wholesaler's permit may not be less than $300 or more than $500 annually.

Section 6. Subsections (1) and (3) of section 499.065, Florida Statutes, are amended to read:

499.065 Imminent danger.--

(1) Notwithstanding s. 499.051, the department shall inspect each prescription drug wholesale establishment, prescription drug repackager establishment, veterinary prescription drug wholesale establishment, limited prescription drug veterinary wholesaler establishment, and retail pharmacy drug wholesaler establishment that is required to be permitted under this chapter as often as necessary to ensure compliance with applicable laws and rules. The department shall have the right of entry and access to these facilities at any reasonable time.

(3) The department may determine that a prescription drug wholesale establishment, prescription drug repackager establishment, veterinary prescription drug wholesale establishment, limited prescription drug veterinary wholesaler establishment, or retail pharmacy drug wholesaler establishment that is required to be permitted under this chapter is an imminent danger to the public health and shall require its immediate closure if the establishment fails to comply with applicable laws and rules and, because of the failure, presents

an imminent threat to the public's health, safety, or welfare. Any establishment so deemed and closed shall remain closed until allowed by the department or by judicial order to reopen.

For purposes of this section, a refusal to allow entry to the department for inspection at reasonable times, or a failure or refusal to provide the department with required documentation for purposes of inspection, constitutes an imminent danger to the public health.

Section 7. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 685**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Homan offered the following:

Amendment (with directory and title amendments)

Remove line(s) 168-170 and insert:

1. The person is engaged in the business of wholesaling prescription and veterinary legend drugs to persons:

a. Licensed as veterinarians practicing on a full time basis; or

b. Regularly and lawfully engaged in instruction in veterinary medicine; or

c. Regularly and lawfully engaged in law enforcement; or

d. For use in research, not involving clinical use; or

e. Chemical analysis or physical testing, for the purposes of instruction in law enforcement, research, or testing.